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Chong et al.

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(54) **RESERVOIR PRESSURE EQUALIZATION SYSTEMS AND METHODS**

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A61M 5/24 (2006.01)
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A61M 1/00 (2006.01)

(52) **U.S. Cl.**

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(58) **Field of Classification Search**

USPC 604/118, 131, 890.1, 148, 187, 200, 604/201, 122, 411, 414, 415

See application file for complete search history.

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Primary Examiner — Bhisma Mehta

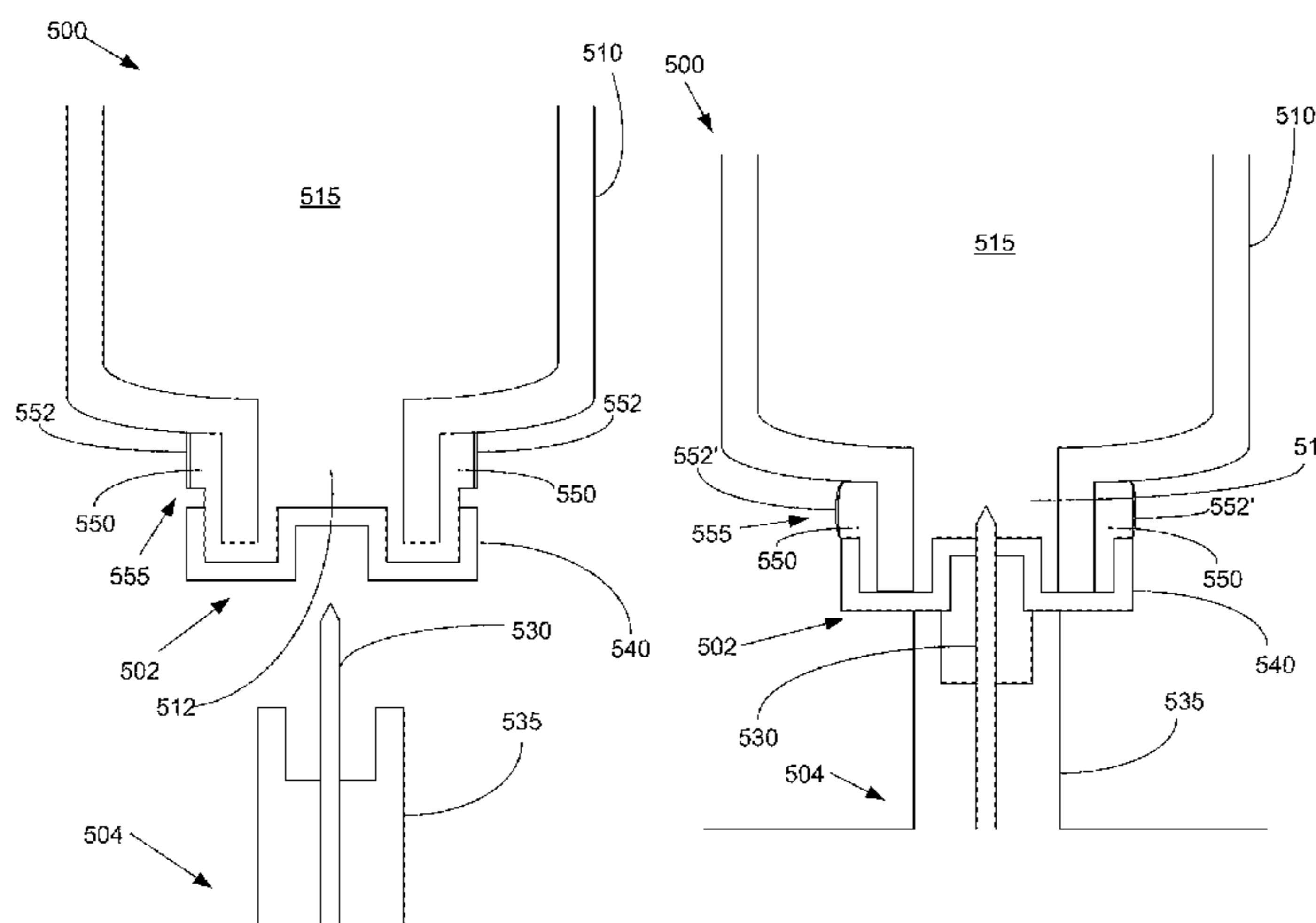
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(57) **ABSTRACT**

Various embodiments of the present invention are directed to equalizing pressure in a reservoir containing fluidic media, possibly due to imperfect installation of the reservoir or an external influence such as an altitude or a temperature change. In various embodiments, fluidic media may be expelled from the reservoir through a needle and contained in an interior volume of a pierceable member before the needle pierces the pierceable member to establish a flow path to a user. In other embodiments, fluidic media may be expelled through a port of the reservoir into a chamber. In further embodiments, fluidic media may be expelled through a channel in a plunger head and out a passage in the reservoir when the channel and passage are aligned. In other embodiments, fluidic media may be expelled through a valve, and the valve may be pierceable by a needle to establish a flow path to the user.

27 Claims, 19 Drawing Sheets



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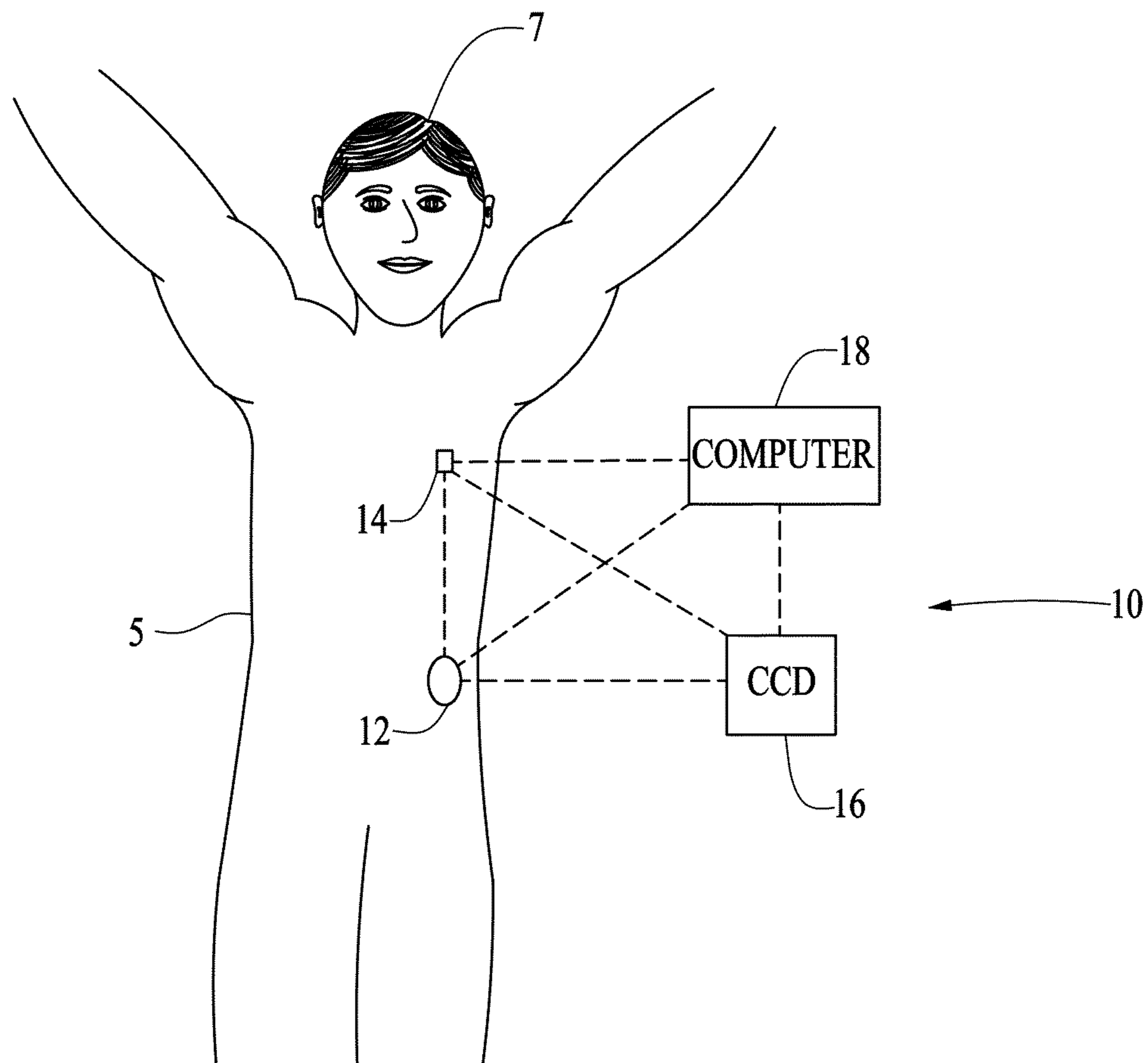


FIG. 1

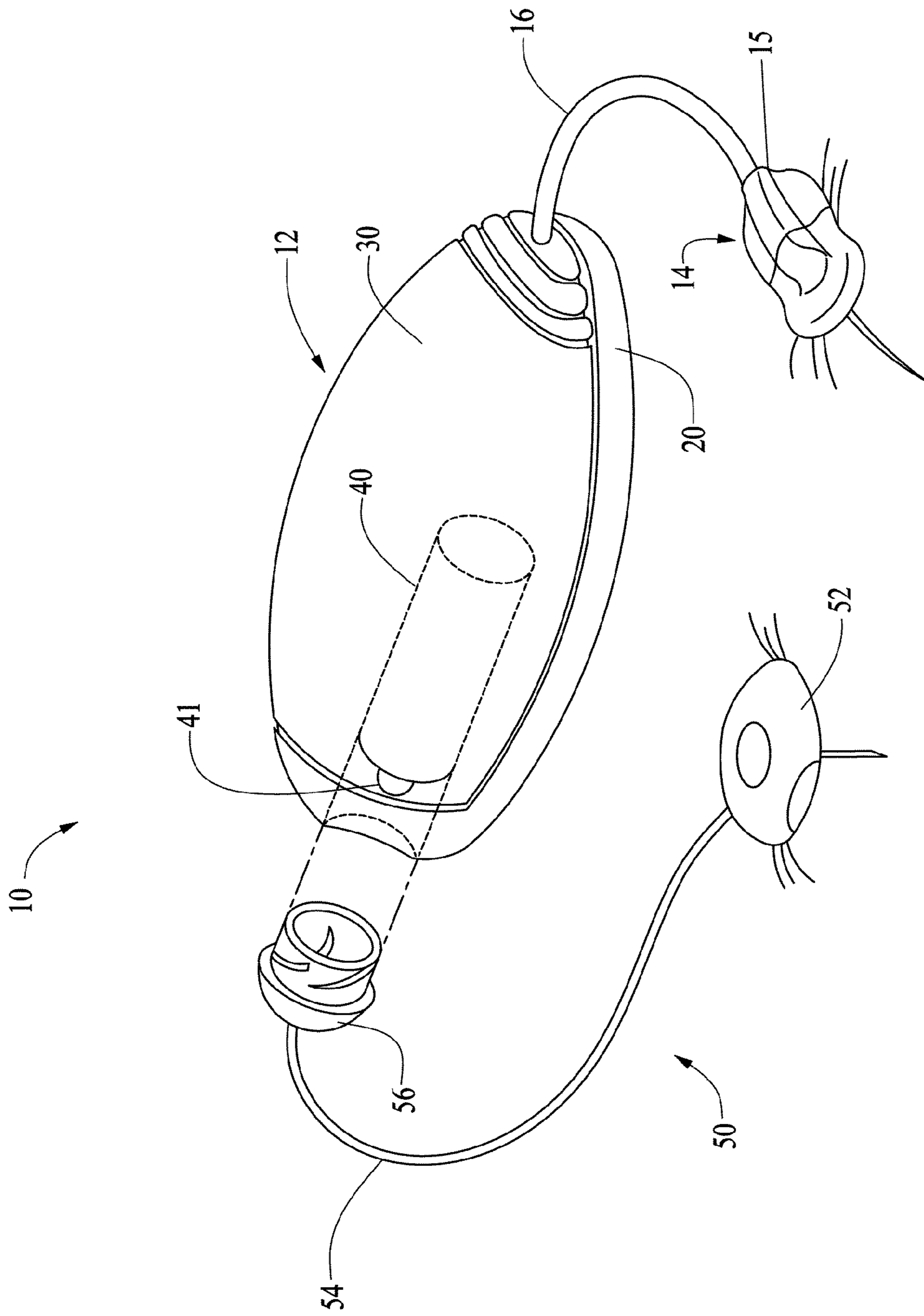


FIG. 2

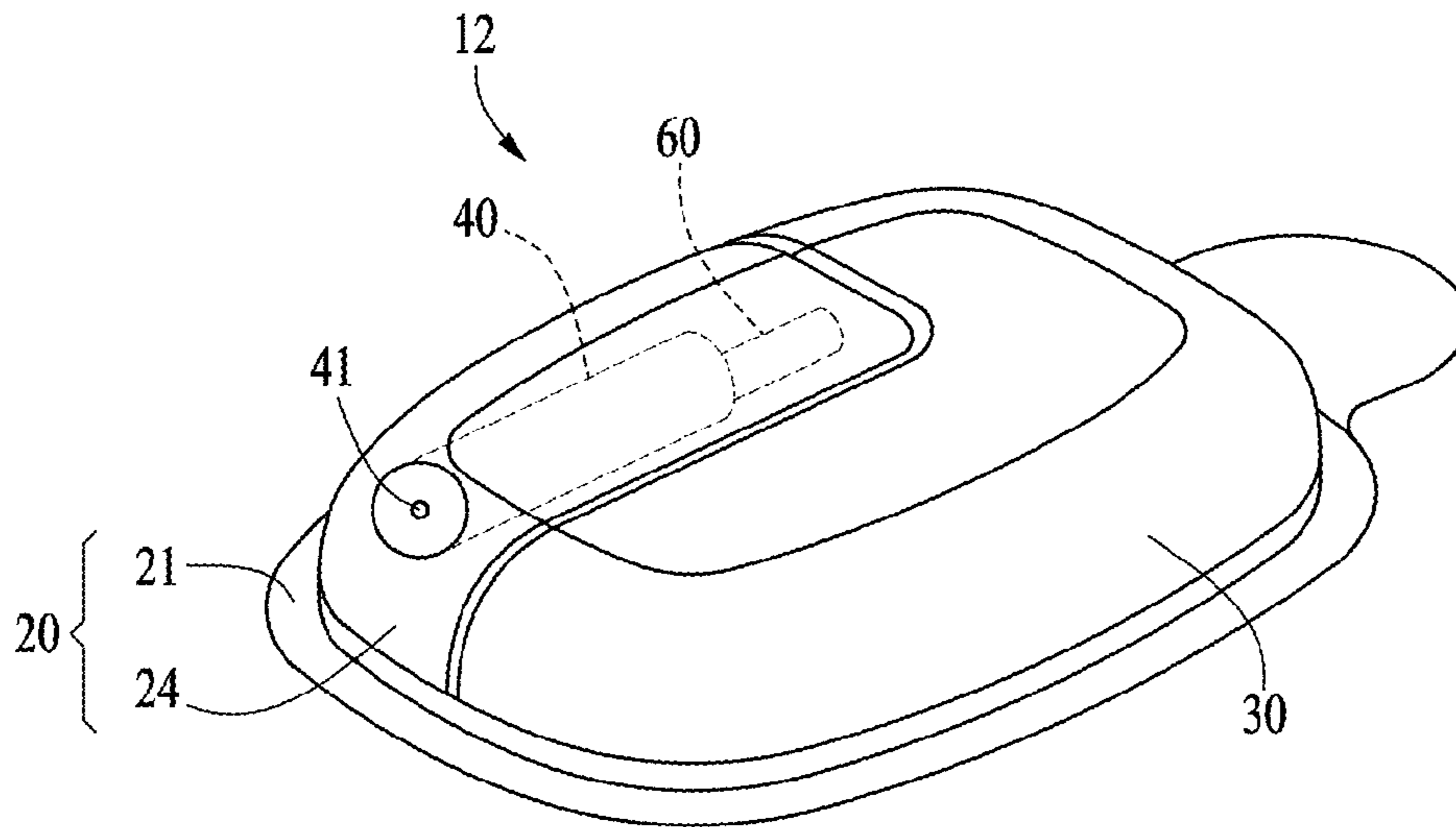


FIG. 3

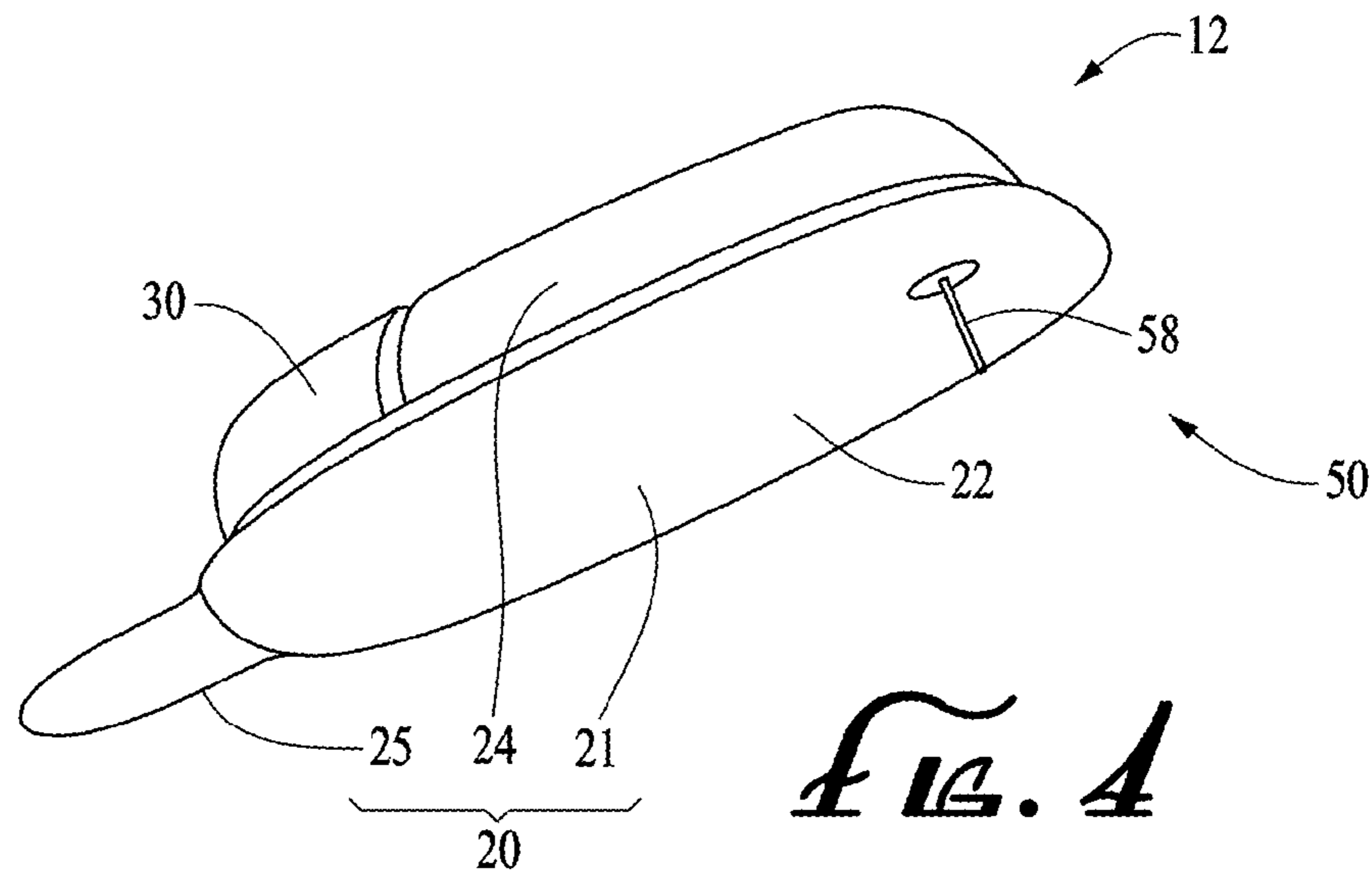
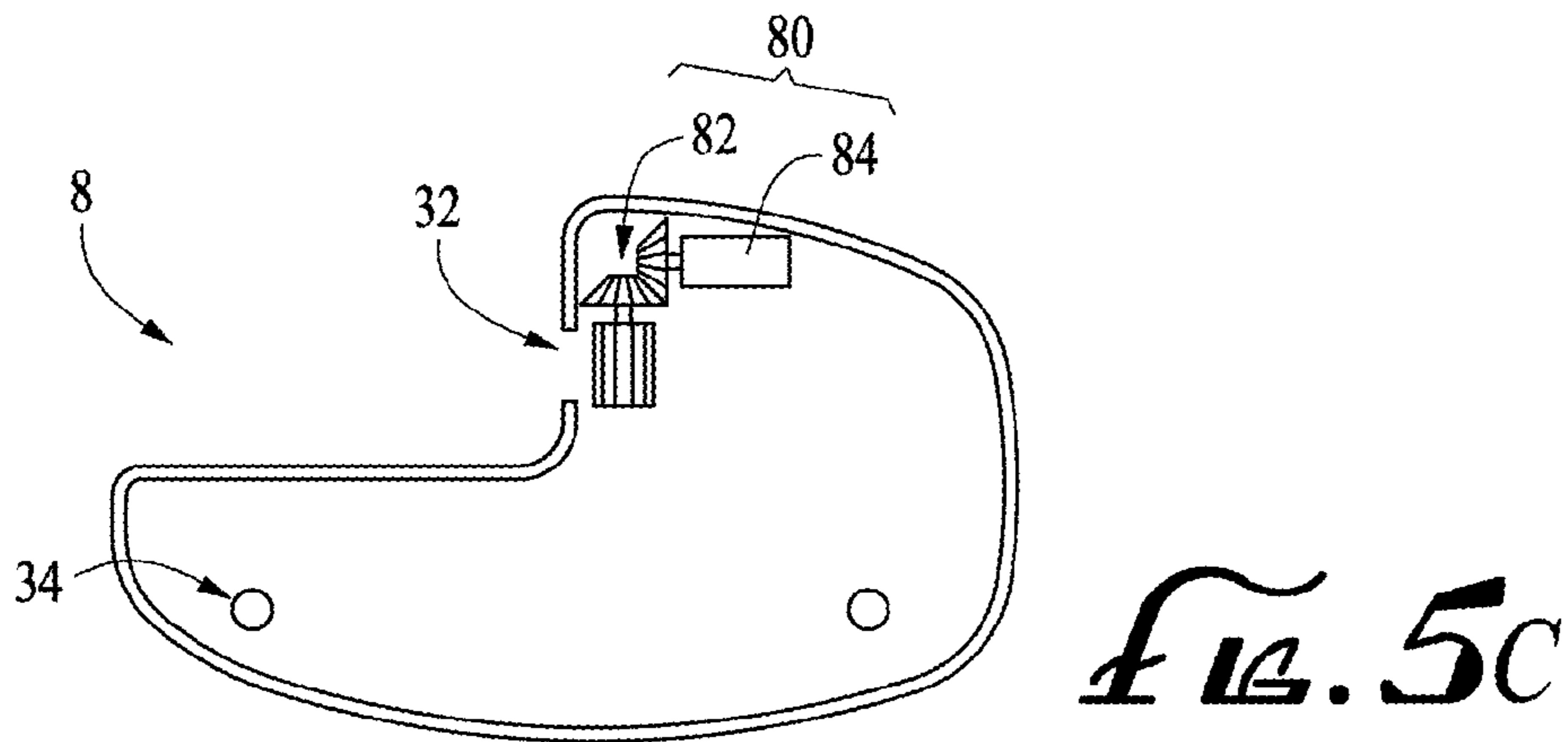
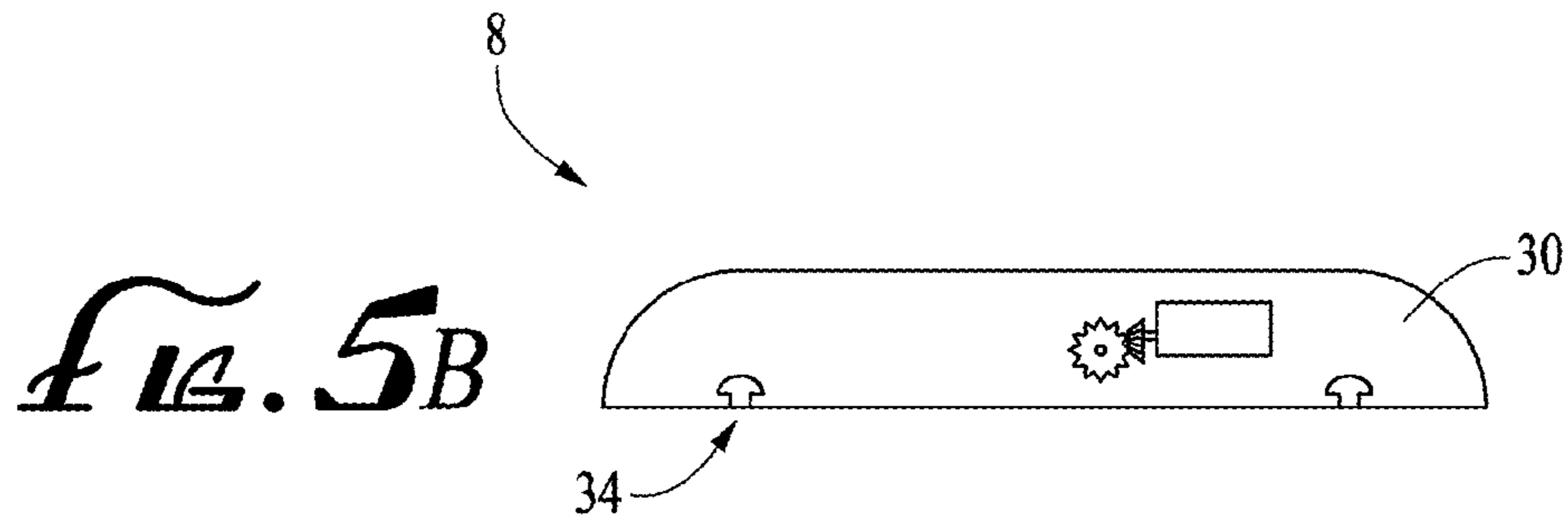
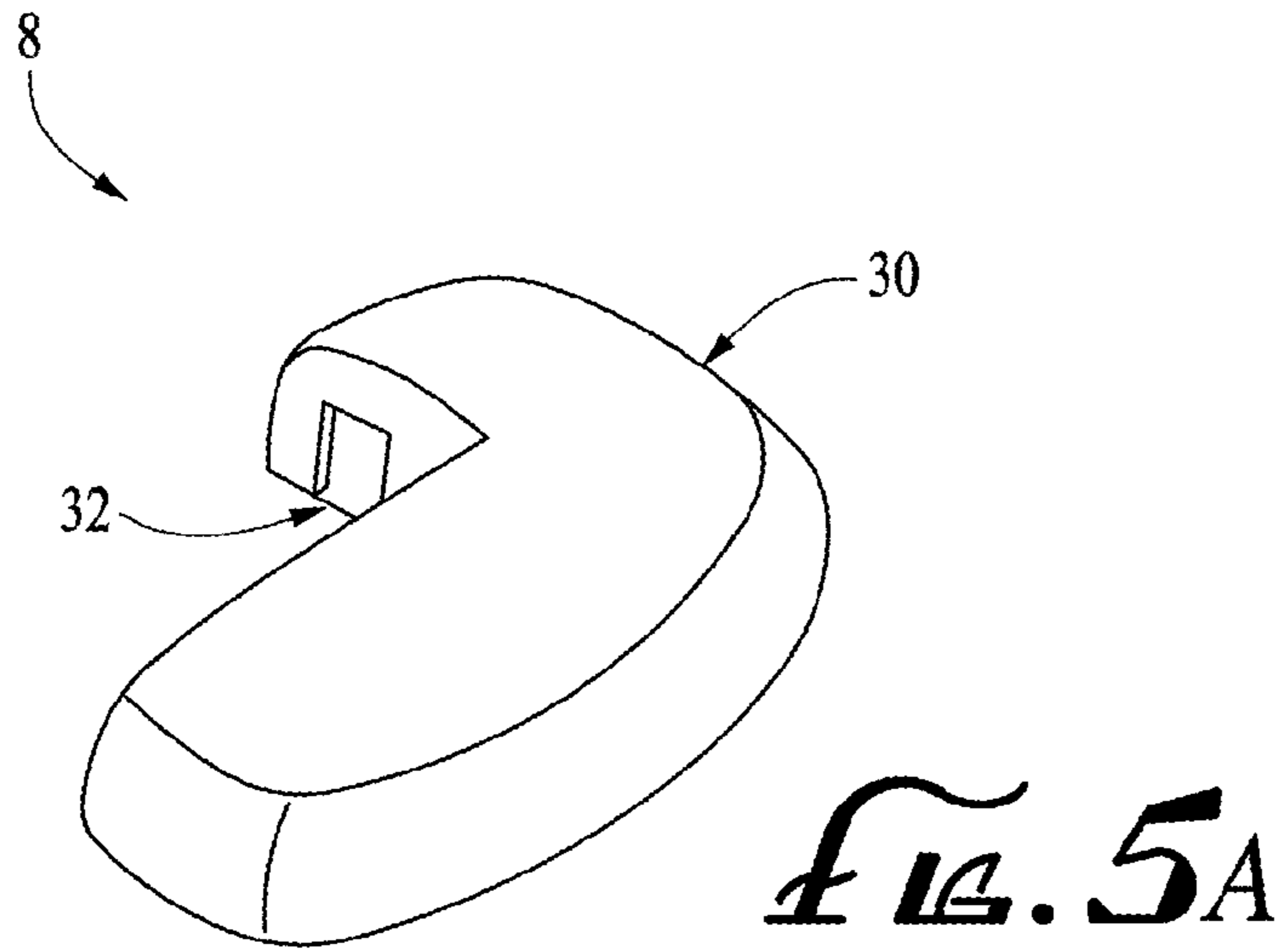
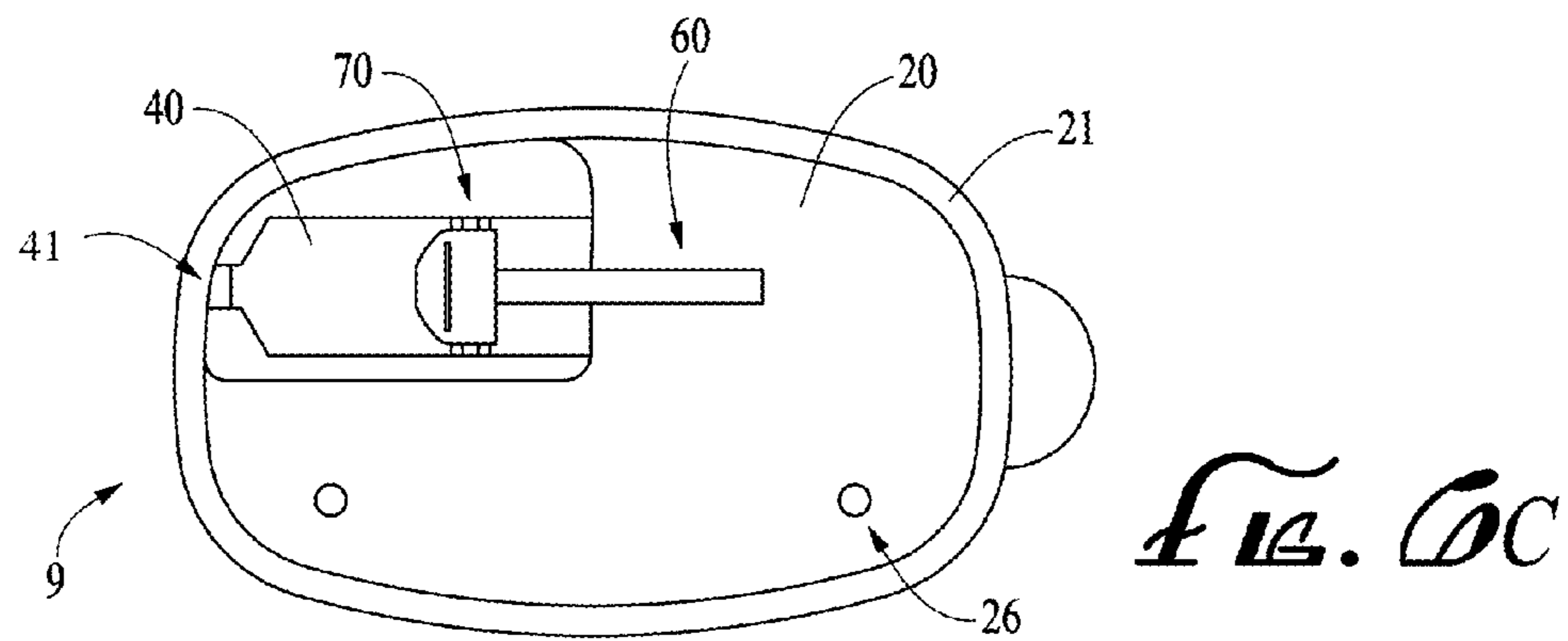
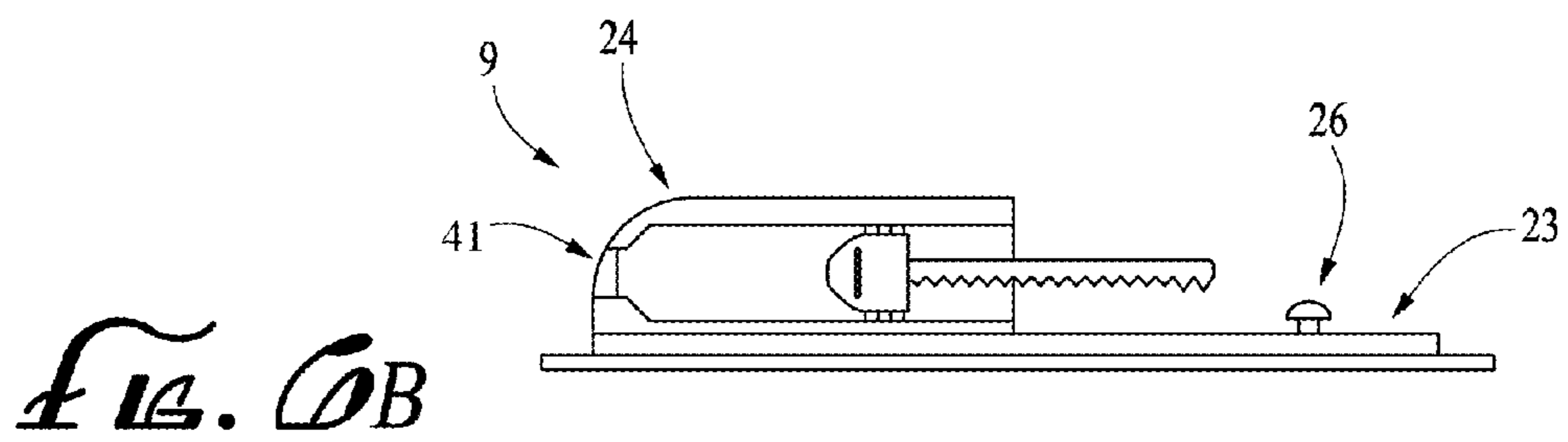
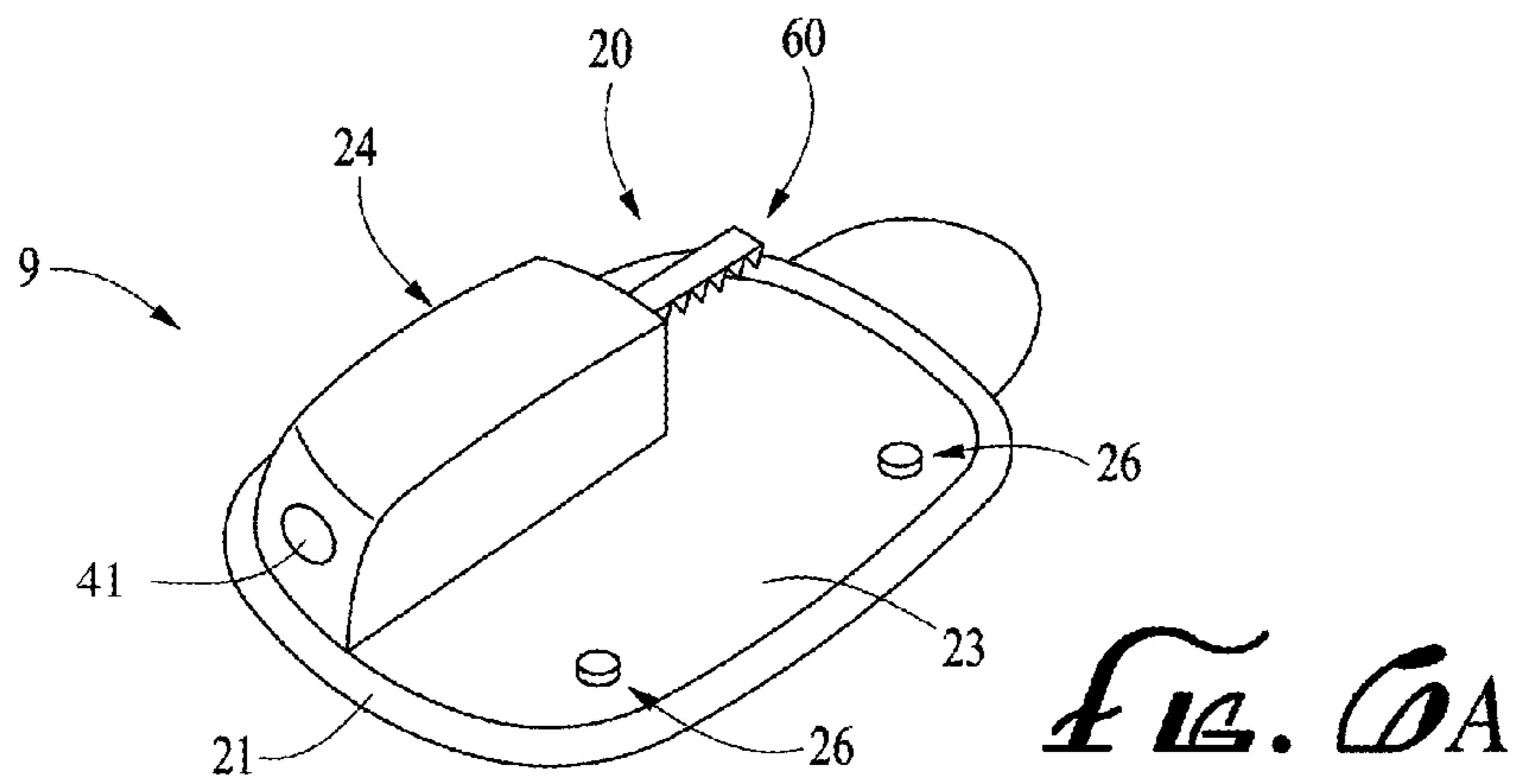


FIG. 4





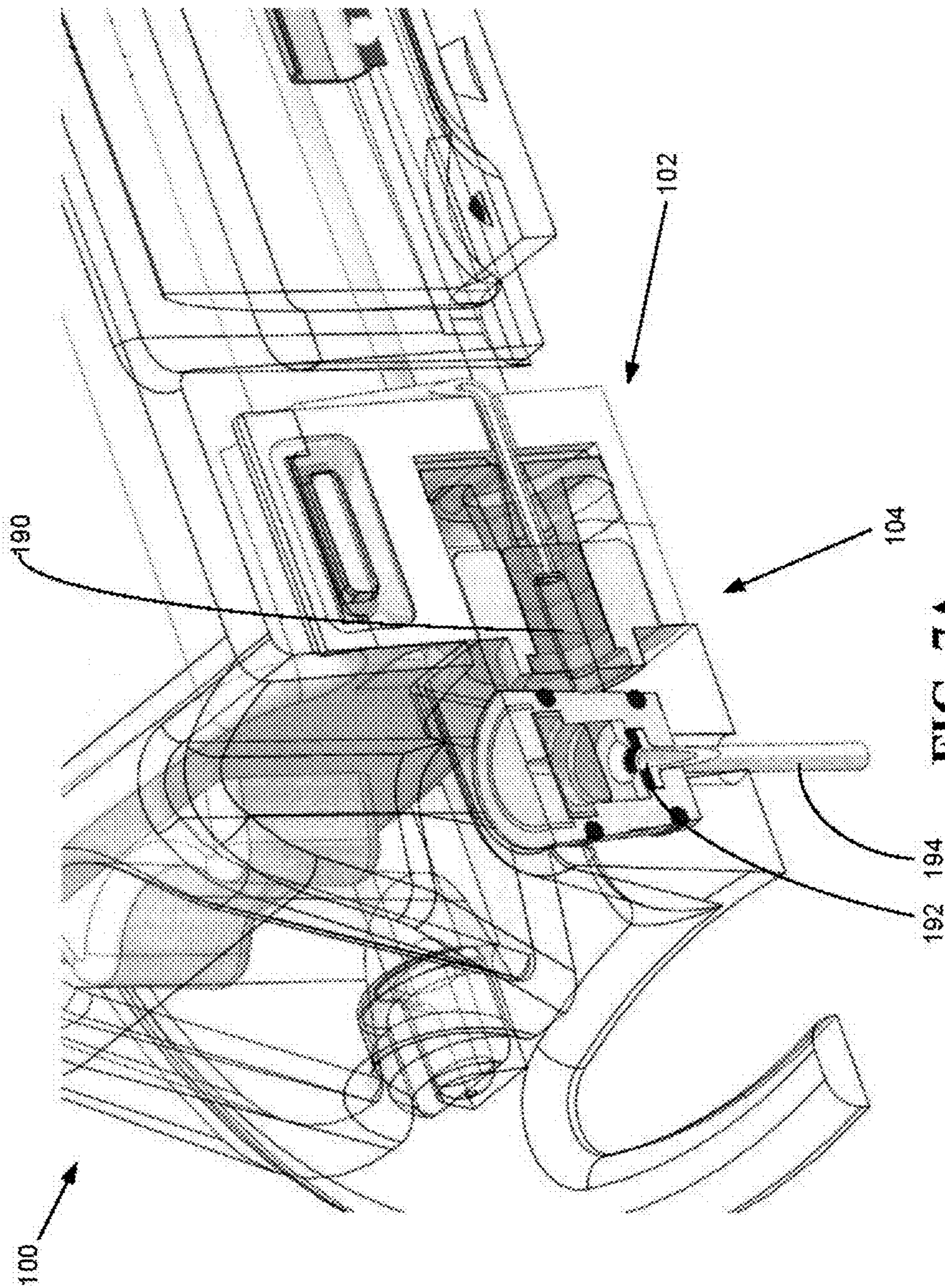


FIG. 7A

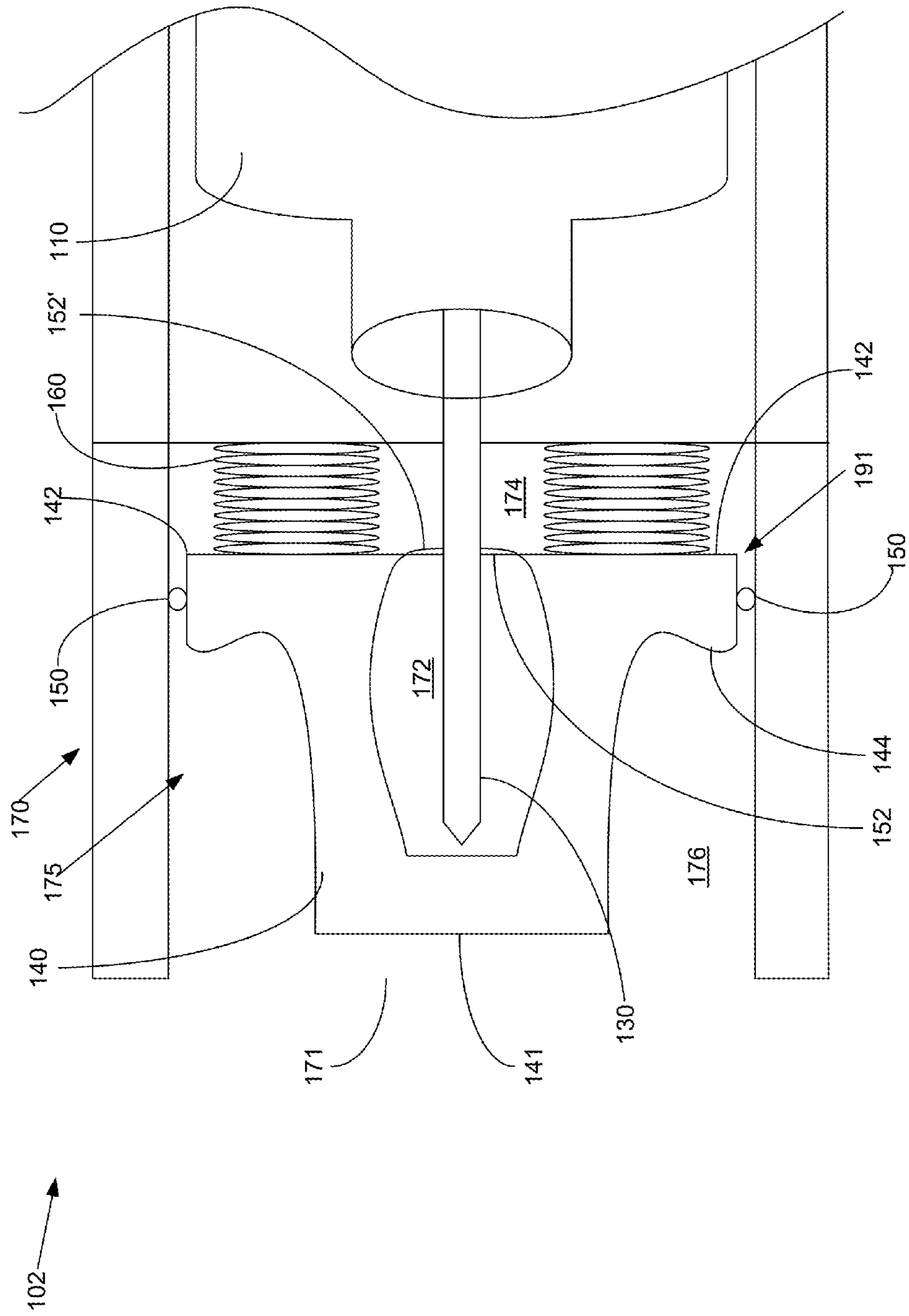


FIG. 7B

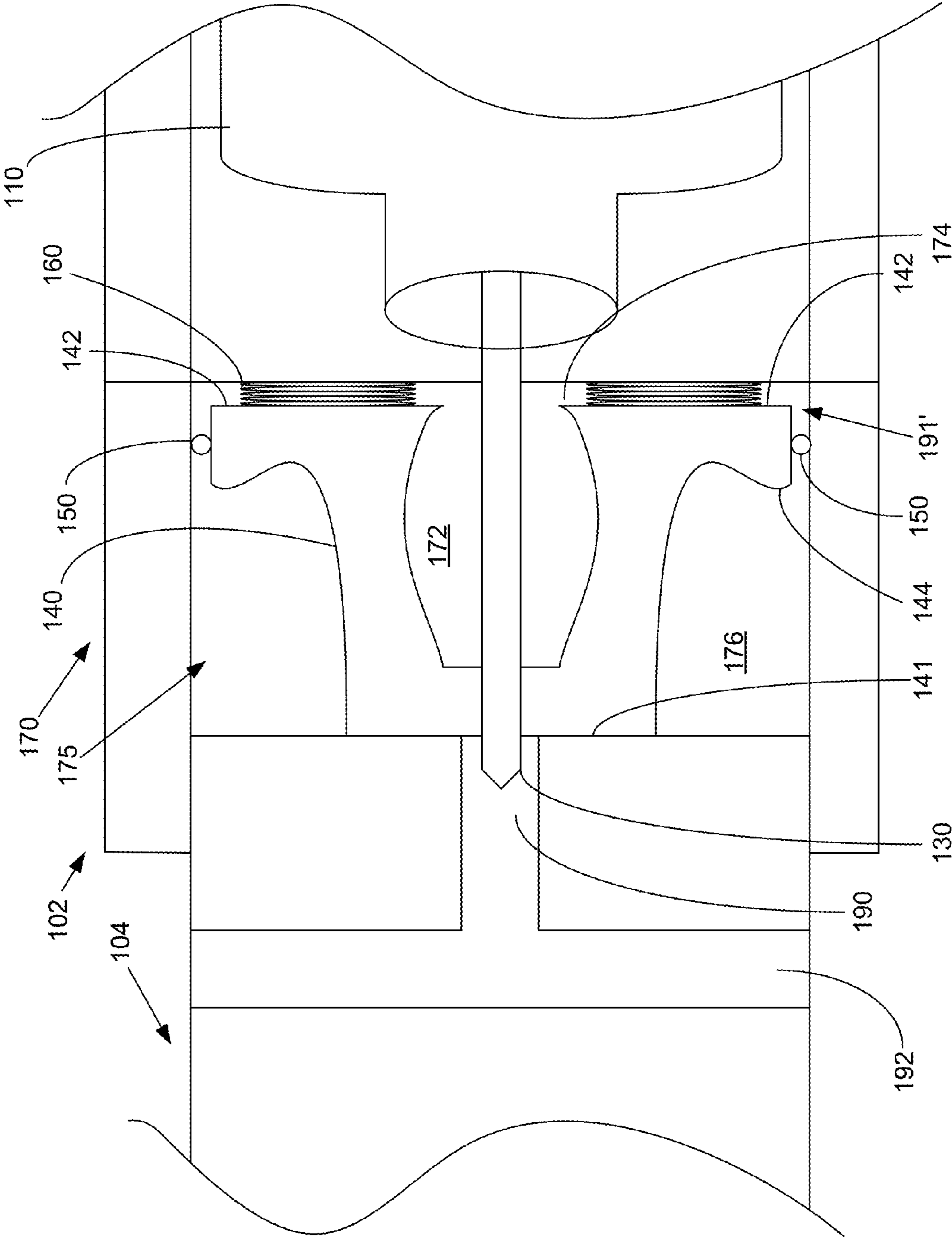


FIG. 7C

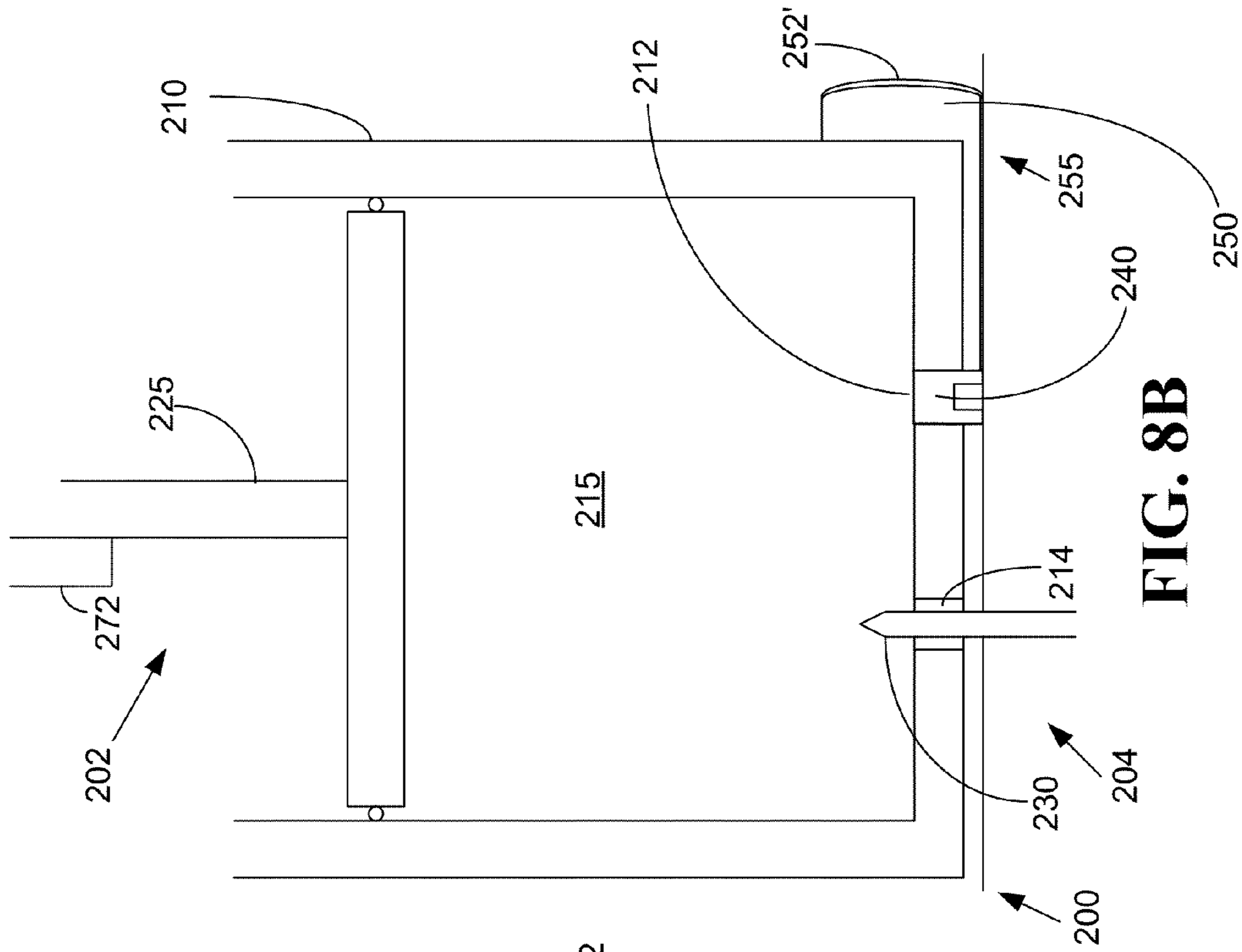


FIG. 8A

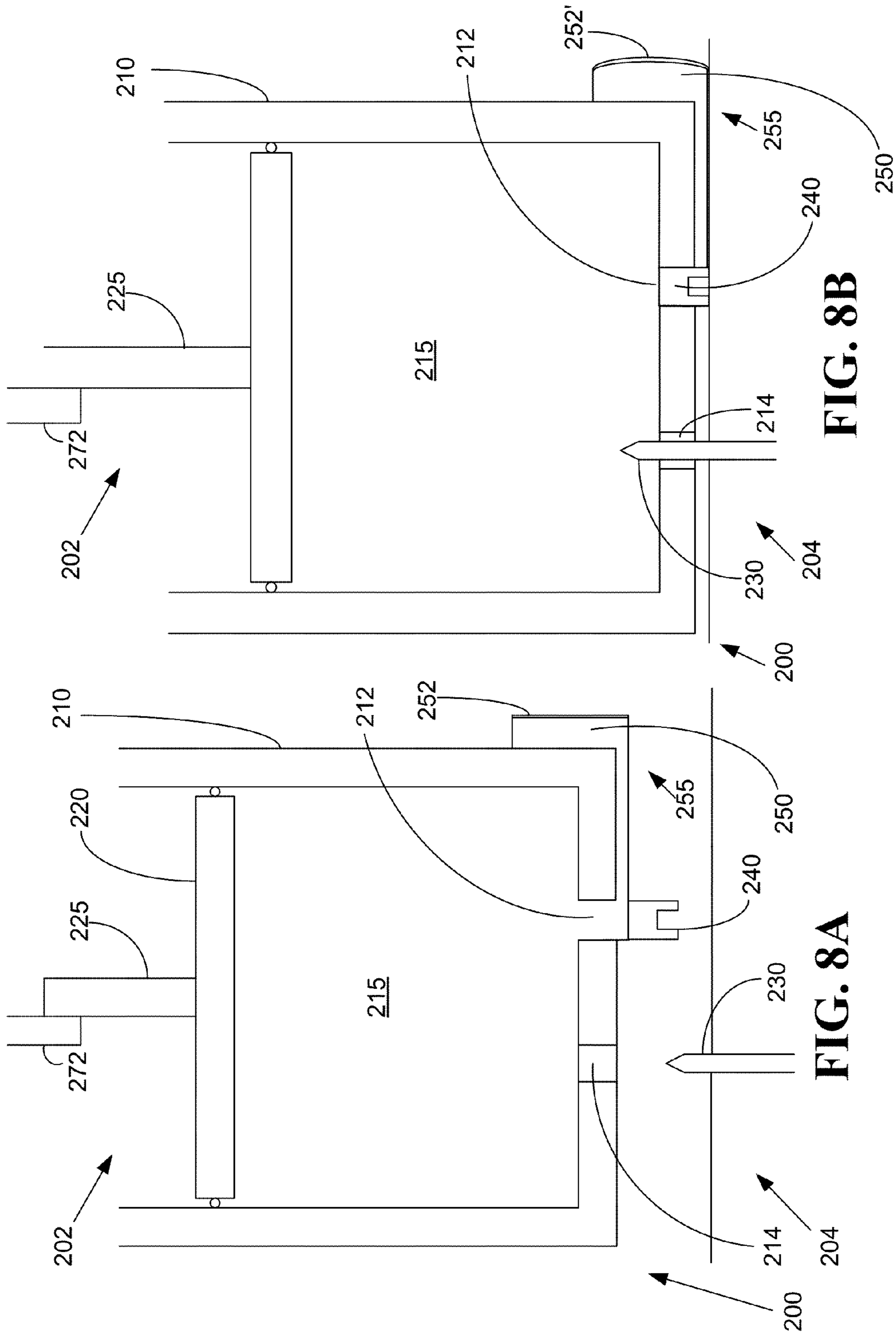


FIG. 8B

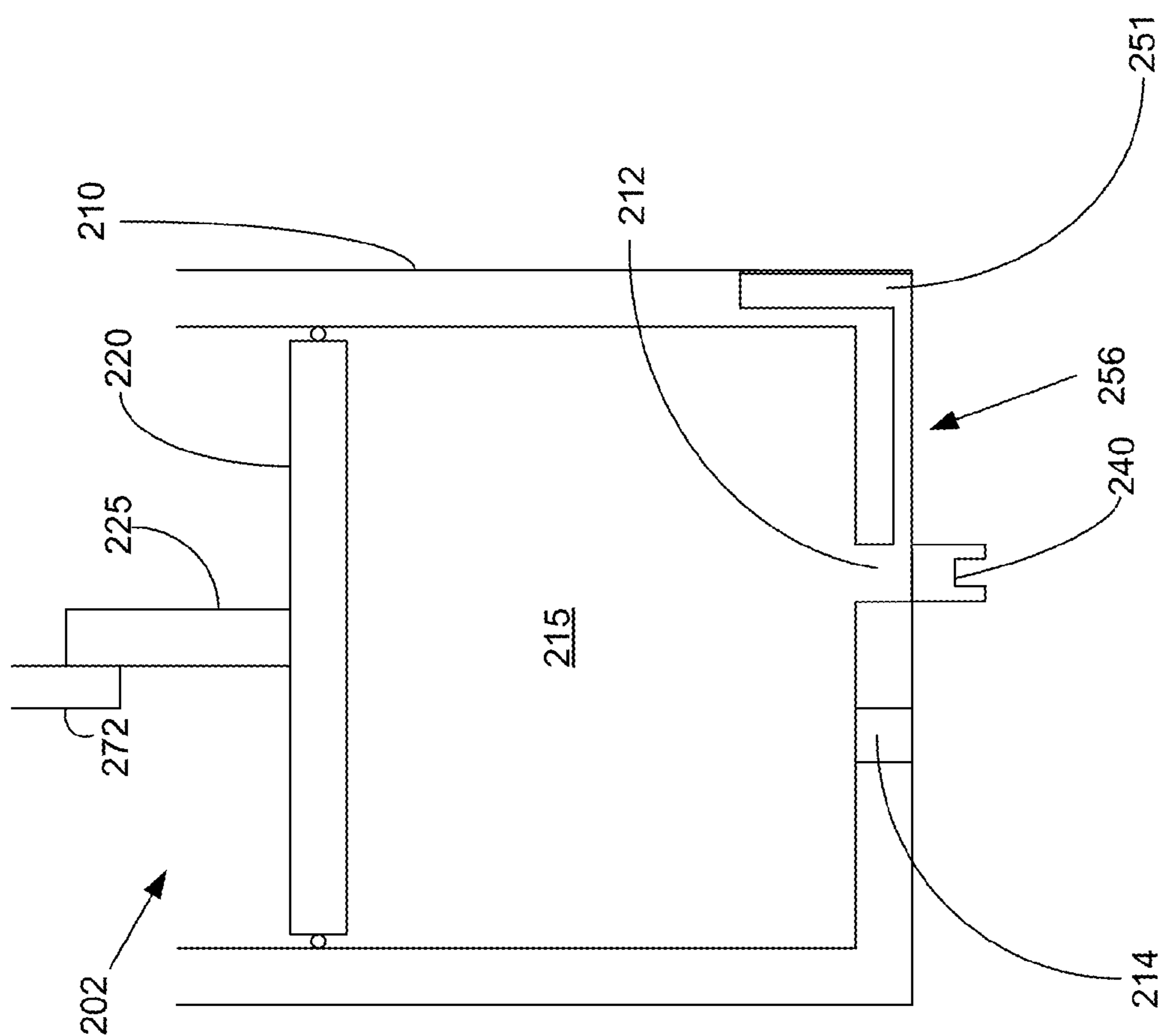


FIG. 8C

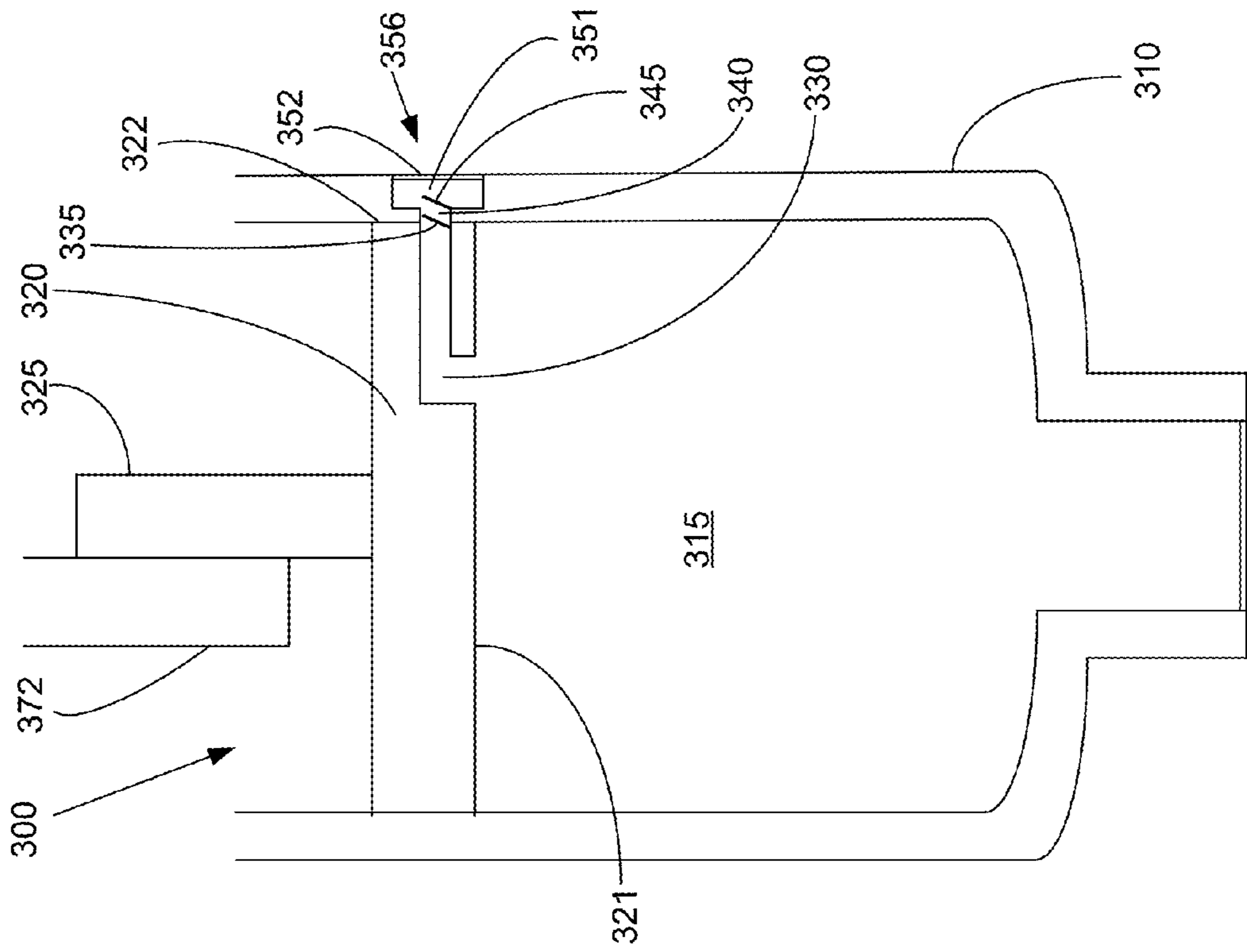


FIG. 9C

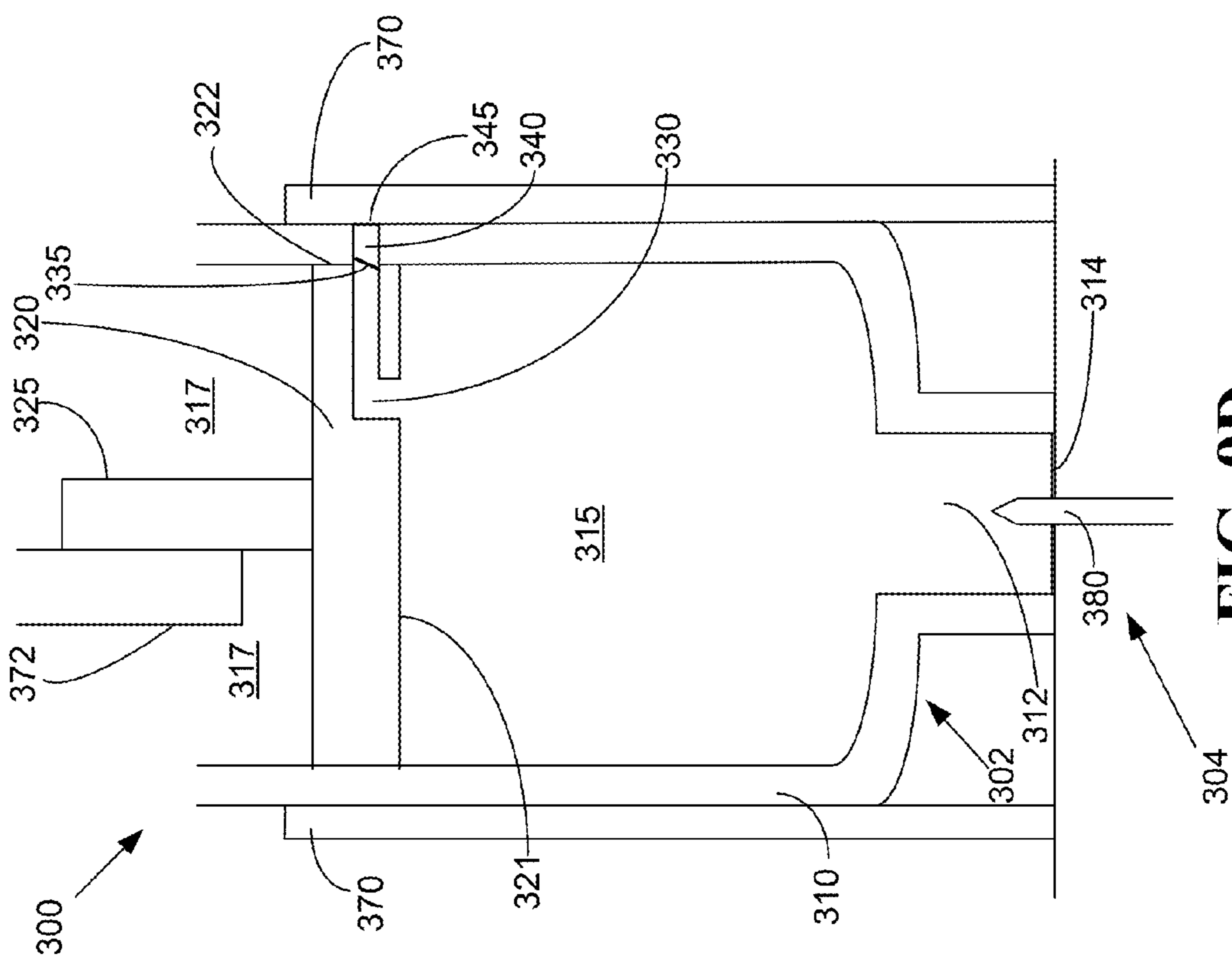


FIG. 9D

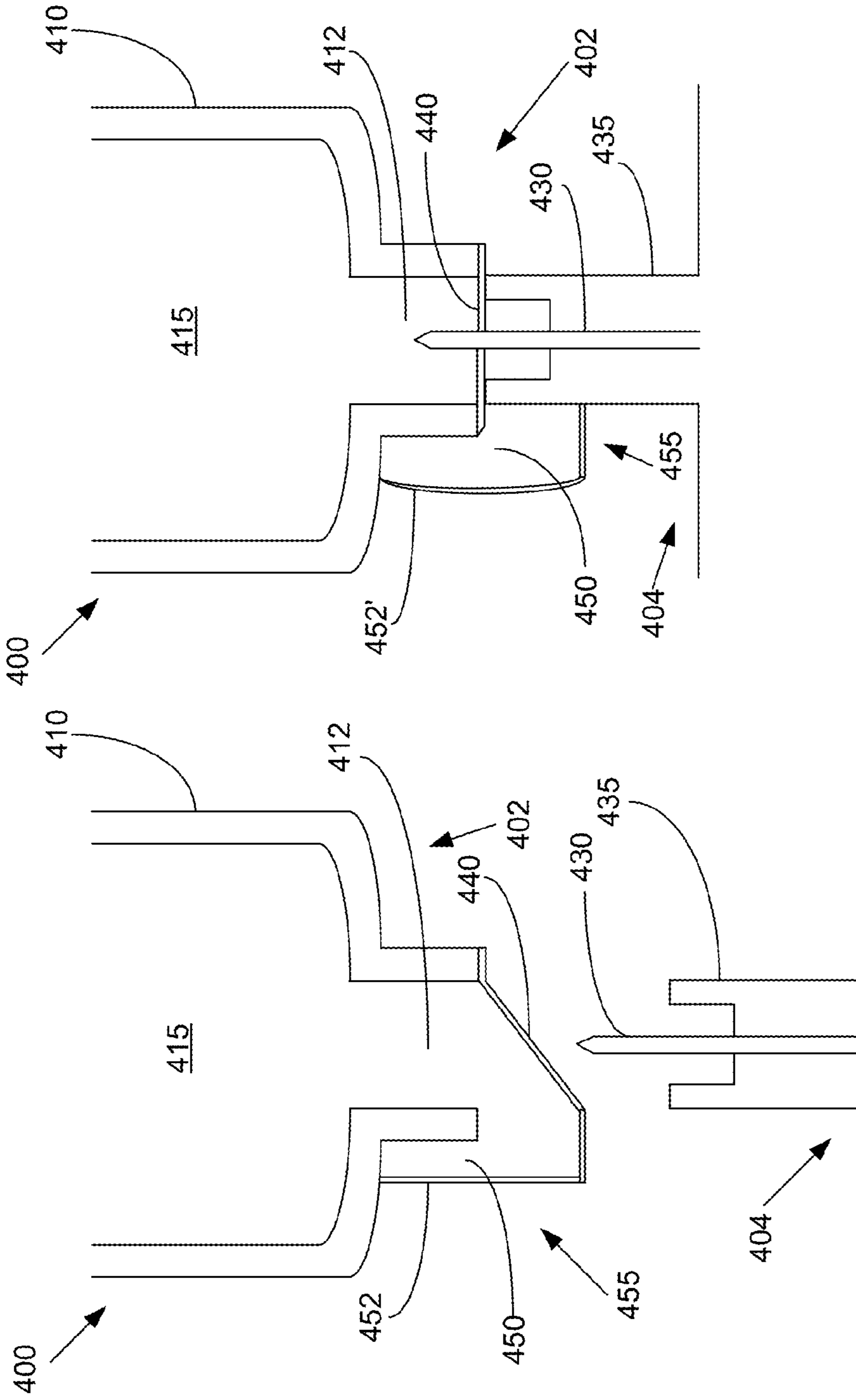


FIG. 10A

FIG. 10B

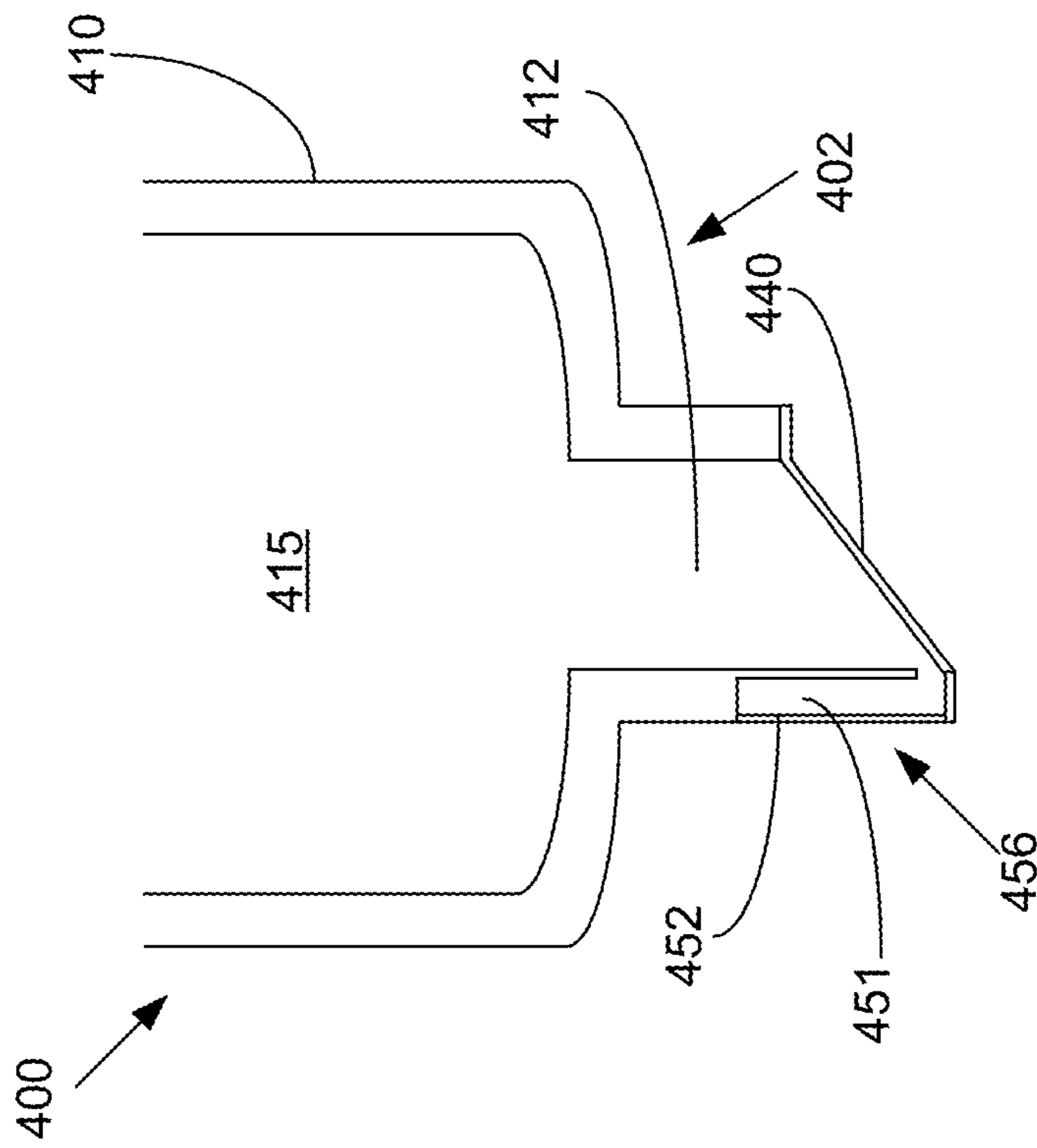
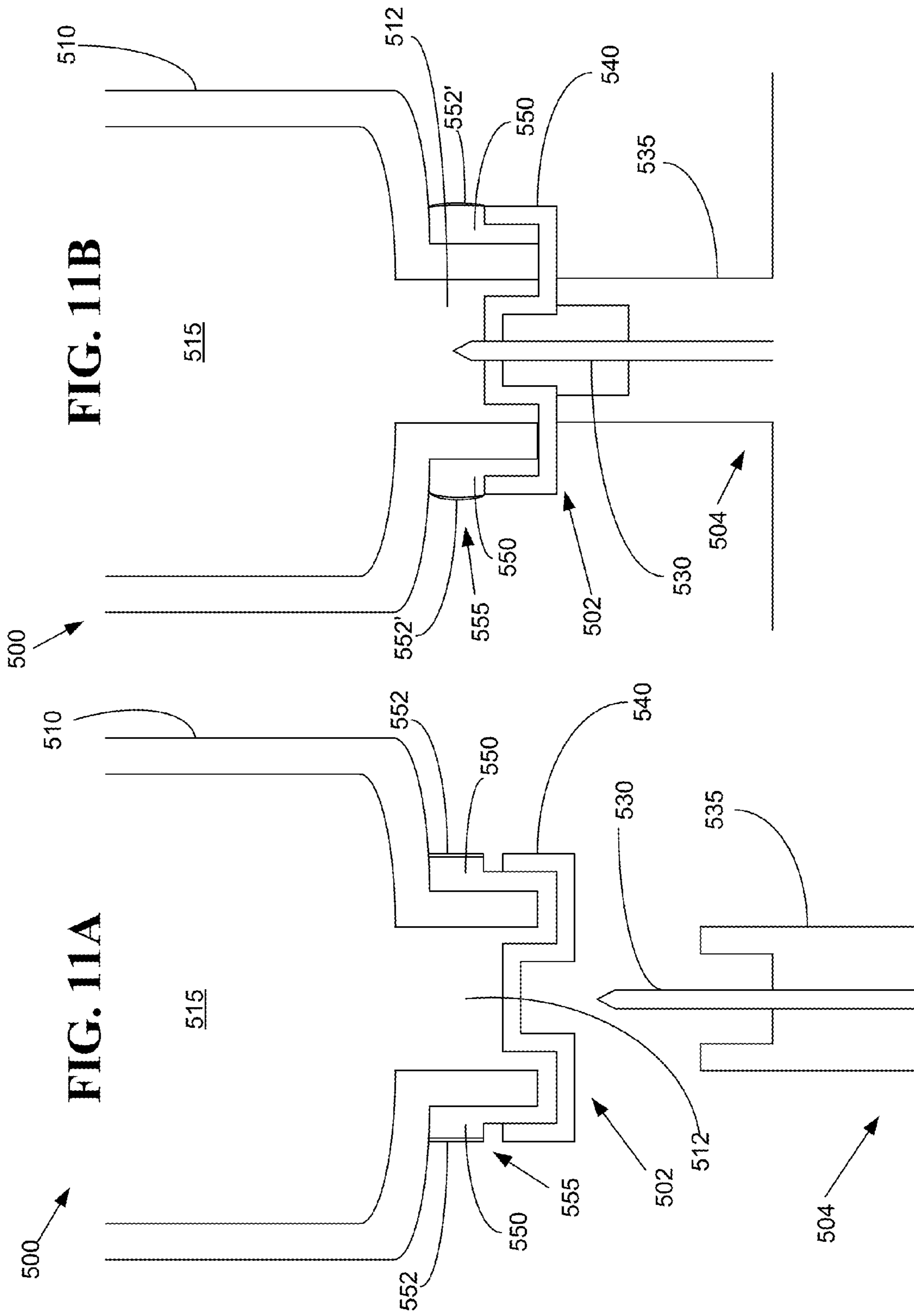
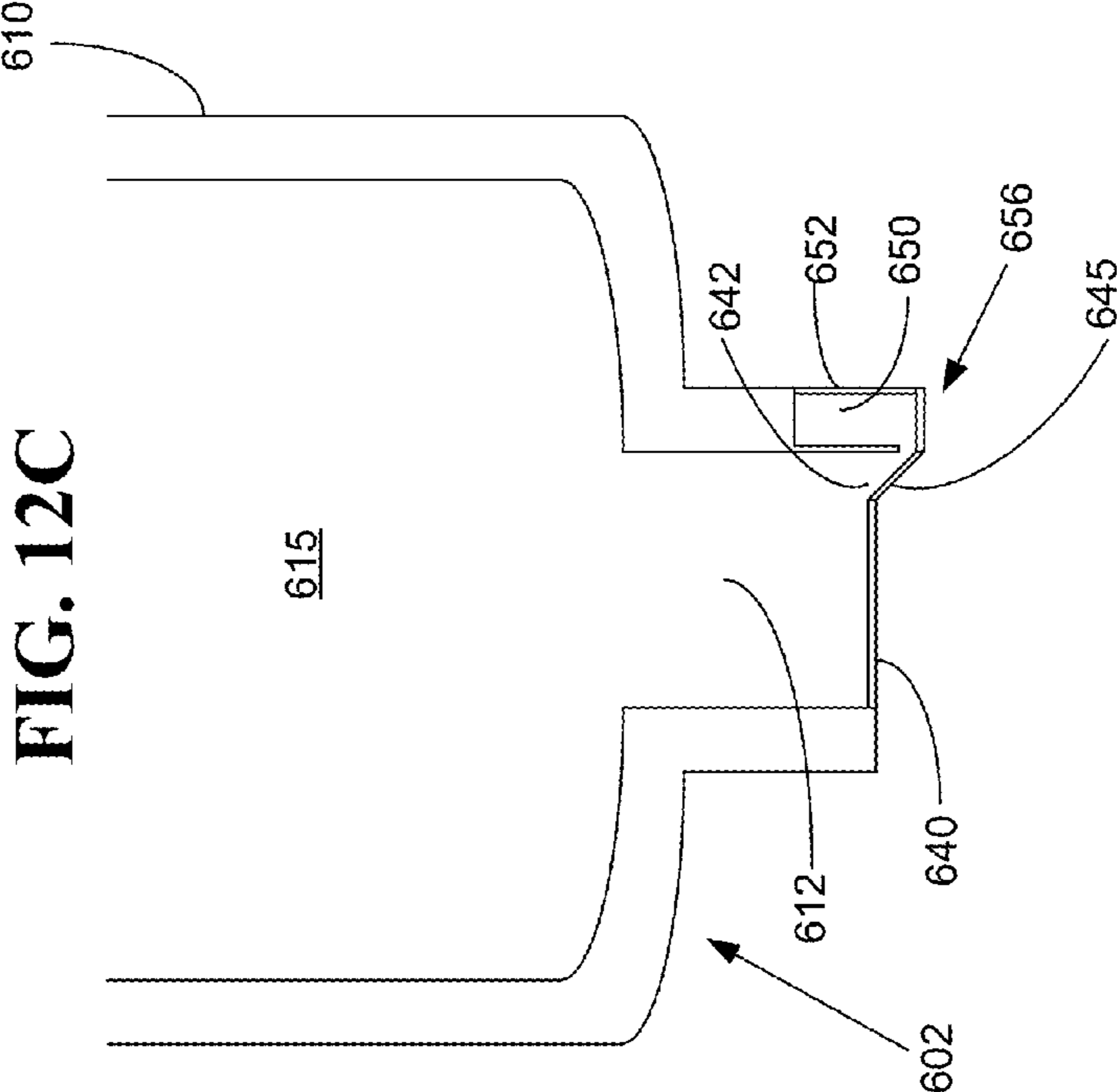


FIG. 10C





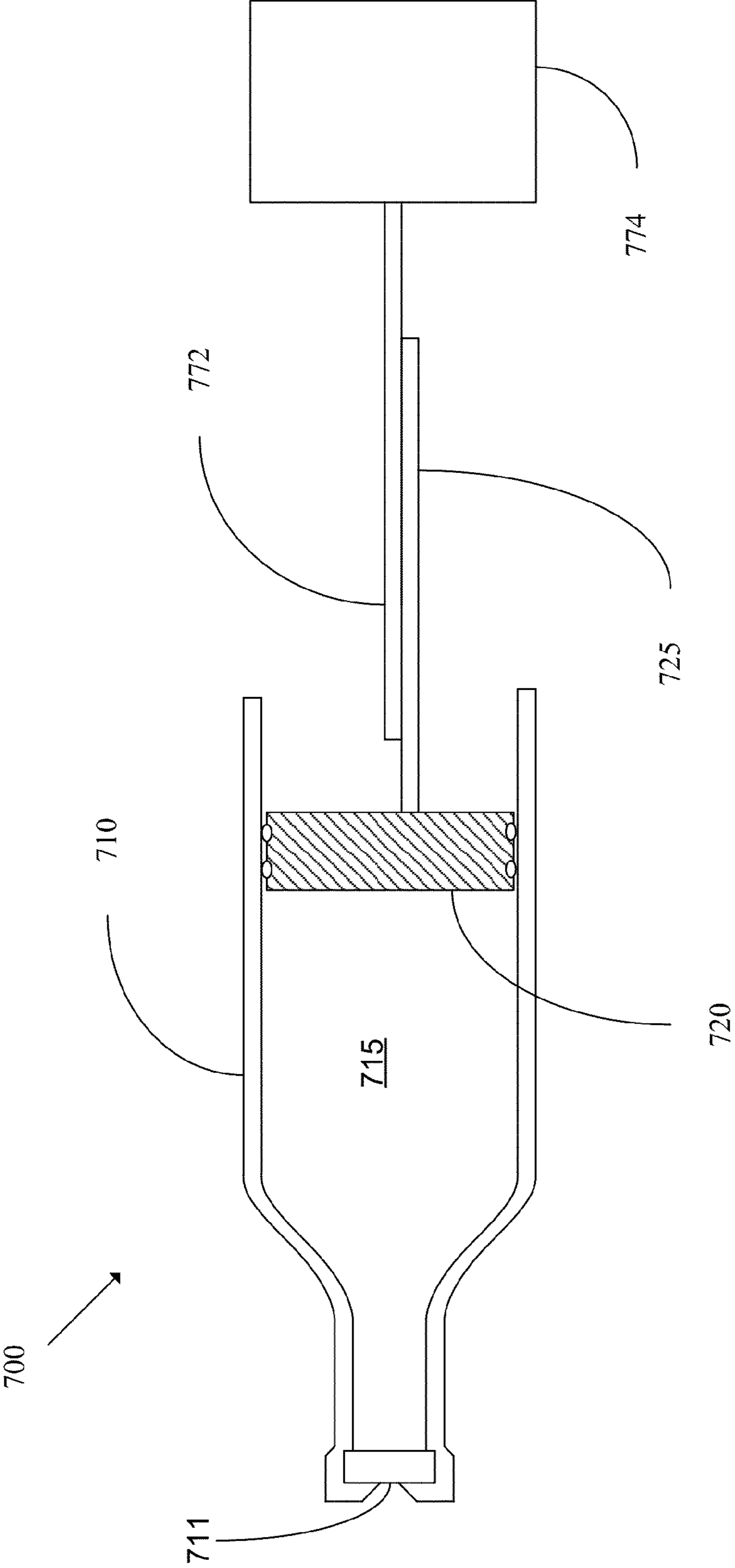


FIG. 13
(PRIOR ART)

RESERVOIR PRESSURE EQUALIZATION SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application is a Division of U.S. application Ser. No. 13/411,278, filed Mar. 2, 2012, which is a Division of U.S. Ser. No. 11/965,578, filed Dec. 27, 2007, incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

Embodiments of the present invention relate generally to systems and methods with reservoirs and, in specific embodiments, to systems and methods allowing for pressure equalization of fluidic media contained within the reservoirs.

2. Related Art

According to modern medical techniques, certain chronic diseases may be treated by delivering a medication or other substance to the body of a patient. For example, diabetes is a chronic disease that is commonly treated by delivering defined amounts of insulin to a patient at appropriate times. Traditionally, manually operated syringes and insulin pens have been employed for delivering insulin to a patient. More recently, modern systems have been designed to include programmable pumps for delivering controlled amounts of medication to a patient.

Pump type delivery devices have been configured in external devices, which connect to a patient, and have also been configured in implantable devices, which are implanted inside of the body of a patient. External pump type delivery devices include devices designed for use in a stationary location, such as a hospital, a clinic, or the like, and further include devices configured for ambulatory or portable use, such as devices that are designed to be carried by a patient, or the like. External pump type delivery devices may contain reservoirs of fluidic media, such as, but is not limited to, insulin. External pump type delivery devices may be connected in fluid flow communication to a patient or user, for example, through a suitable hollow tubing. The hollow tubing may be connected to a hollow needle that is designed to pierce the skin of the patient and to deliver fluidic media there through. Alternatively, the hollow tubing may be connected directly to the patient as through a cannula, or the like.

Examples of some external pump type delivery devices are described in the following references: (i) Published PCT Application WO 01/70307 (PCT/US01/09139), entitled "Exchangeable Electronic Cards for Infusion Devices"; (ii) Published PCT Application WO 04/030716 (PCT/US2003/028769), entitled "Components and Methods for Patient Infusion Device"; (iii) Published PCT Application WO 04/030717 (PCT/US2003/029019), entitled "Dispenser Components and Methods for Infusion Device"; (iv) U.S. Patent Application Pub. No. 2005/0065760, entitled "Method for Advising Patients Concerning Doses Of Insulin"; and (v) U.S. Pat. No. 6,589,229, entitled "Wearable Self-Contained Drug Infusion Device", each of which is incorporated by reference herein in its entirety.

As compared to syringes and insulin pens, pump type delivery devices can be significantly more convenient to a patient, in that doses of insulin may be calculated and delivered automatically to a patient at any time during the day or night. Furthermore, when used in conjunction with glucose sensors or monitors, insulin pumps may be automatically controlled to provide appropriate doses of fluidic media at

appropriate times of need, based on sensed or monitored levels of blood glucose. As a result, pump type delivery devices have become an important aspect of modern medical treatments of various types of medical conditions, such as diabetes, and the like. As pump technologies improve and doctors and patients become more familiar with such devices, external medical infusion pump treatments are expected to increase in popularity and are expected to increase substantially in number over the next decade.

However, one of the problems with pump type delivery devices is that a bolus of fluidic media could be delivered inadvertently to the patient in a case where the reservoir of fluidic media is pressurized. FIG. 13 illustrates a conventional reservoir system 700. The reservoir system 700 may include a reservoir 710 with an interior volume 715 filled with fluidic media, a plunger head 720, a plunger shaft 725, and a driveshaft 772 mechanically connected to a drive motor 774. The reservoir 710 may include a self-sealing septum 711. When the reservoir 710 is inserted in the reservoir system 700, the plunger shaft 725 mechanically couples with the driveshaft 772 by use of complementing mating parts, such as threads, for example. If the complementing threads of the plunger shaft 725 and the driveshaft 772 are not perfectly aligned, the plunger shaft 725 shifts a small distance, such as a half thread forward or backward, so that the threads can align and couple together. Accordingly, the plunger head 720, which is connected to the plunger shaft 725, is moved a half thread forward or backward within the reservoir 710. If the plunger head 720 is moved forward, pressure in the interior volume 715 of the reservoir 710 is increased. As a result, this could cause the reservoir system 700 inadvertently to pump a small bolus of fluidic media to a user once a fluid path between the reservoir system 700 and the user is established. Alternatively, the interior volume 715 of the reservoir 710 could become pressurized due to a change in an external influence such as an altitude or a temperature as well, which could also lead to an inadvertent bolus of fluid being delivered to the user once the fluid path between the reservoir system 700 and the user is established. The opposite effect is true for a system that draws the plunger head backwards, establishing a negative pressure in the reservoir. In this case, bodily fluids may be drawn into the fluid path or reservoir when the fluid system is fully connected.

SUMMARY OF THE INVENTION

Various embodiments of the present invention are directed to equalizing pressure in a reservoir containing fluidic media. This may prevent patients from inadvertently receiving boluses of fluidic media because of increased pressure within a reservoir of a medical device due to, for example, imperfect alignment of a plunger shaft and a driveshaft within the medical device, or a change in an external influence, such as an altitude or a temperature change. Additionally, it may prevent the system from drawing bodily fluids into the reservoir if the reservoir is biased with a negative pressure.

A system for equalizing pressure in a reservoir in accordance with an embodiment of the present invention may include, but is not limited to, a structure, a needle, and a pierceable member. The structure may have a chamber. The needle may be connectable to the reservoir for allowing fluidic media contained in the reservoir to flow through the needle when the needle is connected to the reservoir. The pierceable member may be moveable within the chamber and pierceable by the needle. The pierceable member may have an interior volume for containing fluidic media expelled from the reservoir before the pierceable member is pierced by the

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needle. In some embodiments, the interior volume of the pierceable member may allow for containing fluidic media that flows through the needle from the reservoir before the pierceable member is pierced by the needle. Fluidic media may be expelled from the reservoir in a case where a pressure difference exists between the reservoir and the chamber. In some embodiments, fluidic media may be expelled from the reservoir in a case where a pressure difference exists between the reservoir and the interior volume of the pierceable member. An end of the needle may be located at least substantially within the interior volume of the pierceable member before the pierceable member is pierced by the needle. A cross-section of the pierceable member may be U-shaped.

The system may further include a first housing portion and a second housing portion. The first housing portion may be adapted to be carried by a user. The second housing portion may be configured to be selectively operatively engaged with and disengaged from the first housing portion. The structure may be supported by one of the first and second housing portions. The pierceable member may be positioned to be pierced by the needle when the first housing portion and the second housing portion are operatively engaged. The needle may be positioned to enter the other of the first and second housing portions from the one of the first and second housing portions when the first housing portion and the second housing portion are operatively engaged.

The pierceable member may have a first end and a second end. The first end may be for contacting the other of the first and second housing portions from the one of the first and second housing portions when the first housing portion and the second housing portion are operatively engaged. The second end may be located on an opposite side of the pierceable member from the first end.

The chamber may have a first portion and a second portion. The first portion of the chamber may be adjacent to the second end of the pierceable member. The first portion of the chamber may be for containing fluidic media in a case where fluidic media flows out of the interior volume of the pierceable member. The first portion of the chamber may be located between the pierceable member and the reservoir. The second portion of the chamber may be adjacent to an opposite side of the pierceable member from the first portion of the chamber. The second portion of the chamber may be for containing fluidic media in a case where fluidic media flows out of the first portion of the chamber. The pierceable member may further include a seal member. The structure may have an opening that communicates with the chamber. The opening may allow for fluidic media to be purged from the chamber in a case where fluidic media flows out of the interior volume of the pierceable member.

The system may further include a bias member. The bias member may be arranged to impart a bias force on the pierceable member. The bias member may be a spring. In other embodiments, the pierceable member may have a resiliently flexible portion. The resiliently flexible portion may be for providing a bias force on the pierceable member to maintain the pierceable member within the chamber. In various embodiments, the needle may have a longitudinal dimension and a central axis along the longitudinal dimension. The interior volume of the pierceable member may be curved concavely relative to the central axis of the needle. In various embodiments, at least one seal member may be positioned between the structure and the pierceable member.

A method for equalizing a pressure within a reservoir may include, but is not limited to, providing a structure having a chamber, locating a needle connectable to the reservoir for allowing fluidic media contained in the reservoir to flow

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through the needle when the needle is connected to the reservoir, and locating a pierceable member moveable within the chamber, where the pierceable member is pierceable by the needle, and where the pierceable member has an interior volume for containing fluidic media expelled from the reservoir before the pierceable member is pierced by the needle.

In an embodiment of a system for equalizing pressure, the system may include, but is not limited to, a reservoir, a plug, and a structure. The reservoir may have a port and an interior volume for containing fluidic media. The plug may be positioned relatively offset to the port of the reservoir. The plug may be for closing the port of the reservoir when the plug is in a closed position. The plug may comprise one of a flapper valve and a disc valve. The structure may have a chamber in flow communication with the interior volume of the reservoir. The chamber may allow for collecting fluidic media expelled from the interior volume of the reservoir through the port in a case where a pressure difference exists between the interior volume of the reservoir and the chamber before the plug is held in the closed position.

The system may further include a first housing portion and a second housing portion. The first housing portion may be adapted to be carried by a user. The second housing portion may be configured to be selectively operatively engaged with and disengaged from the first housing portion. The reservoir may be supported by one of the first and second housing portions. The plug may be positioned to close the port of the reservoir when the first housing portion and the second housing portion are operatively engaged. The other of the first and second housing portions from the one of the first and second housing portions may have a first surface for moving and holding the plug in the closed position when the first housing portion and the second housing portion are operatively engaged.

The system may further include a needle. The needle may be supported by the other of the first and second housing portions from the one of the first and second housing portions. The needle may be for piercing a portion of the reservoir and entering the interior volume of the reservoir when the first housing portion and the second housing portion are operatively engaged. The needle may allow for fluidic media contained in the interior volume of the reservoir to flow through the needle when the needle is in the interior volume of the reservoir. In some embodiments, the portion of the reservoir pierced by the needle when the first housing portion and the second housing portion are operatively engaged may be the plug.

The system may further include a membrane configured to expand to increase the volume of the chamber in a case where the chamber sufficiently fills with fluidic media. The membrane may be an elastomeric membrane. The system may include one of a hydrophobic filter and a hydrophilic filter. The chamber may be located within the reservoir. In some embodiments, the chamber may be located outside of the reservoir. The structure may have an opening that communicates with the chamber, where the opening may allow for fluidic media to be purged from the chamber.

A method for equalizing pressure may include, but is not limited to, providing a reservoir having a port and an interior volume for containing fluidic media, locating a plug positioned relatively offset to the port of the reservoir, where the plug allows for closing the port of the reservoir when the plug is in a closed position, and locating a structure having a chamber in flow communication with the interior volume of the reservoir, where the chamber allows for collecting fluidic media expelled from the interior volume of the reservoir from the port in a case where a pressure difference exists between

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the interior volume of the reservoir and the chamber before the plug is held in the closed position.

In an embodiment of a system for equalizing pressure, the system may include, but is not limited to, a reservoir and a plunger head. The reservoir may have a passage and an interior volume for containing fluidic media. The plunger head may have a first surface and a second surface. The plunger head may have a channel connecting the first surface and the second surface. The plunger head may be moveable within the reservoir to align the channel in the plunger head and the passage in the reservoir. When the channel in the plunger head and the passage in the reservoir are aligned and a pressure difference exists between the interior volume of the reservoir and the passage, fluidic media may be expelled from the interior volume of the reservoir through the passage.

In various embodiments, the interior volume allows for containing fluidic media. In some embodiments, the reservoir may have a second interior volume. The plunger head may be located between the interior volume of the reservoir and the second interior volume of the reservoir. The first surface of the plunger head may be in contact with fluidic media when fluidic media is in the interior volume of the reservoir.

In various embodiments, the passage in the reservoir and the channel in the plunger head may be aligned at a first position of the plunger head in the reservoir. The plunger head may be advanceable from the first position to a second position. The passage in the reservoir and the channel in the plunger head may be disaligned when the plunger head is in the second position.

In various embodiments, the system may further include a first housing portion and a second housing portion. The first housing portion may be adapted to be carried by a user. The second housing portion may be configured to be selectively operatively engaged with and disengaged from the first housing portion. The reservoir may be supported by one of the first and second housing portions.

In various embodiments, the system may further include a mating piece. The mating piece may be supported by the other of the first and second housing portions from the one of the first and second housing portions. The mating piece may be for closing the passage when the first housing portion and the second housing portion are operatively engaged. The system may also include a needle. The needle may be supported by the other of the first and second housing portions from the one of the first and second housing portions. The needle may be for piercing the reservoir and entering the interior volume of the reservoir when the first housing portion and the second housing portion are operatively engaged. The needle may be for allowing fluidic media contained in the interior volume of the reservoir to flow through the needle when the needle is in the interior volume of the reservoir. The plunger head may be advanceable in the reservoir from the first position to the second position before the first housing portion and the second housing portion are operatively engaged. The first surface of the plunger head and the second surface of the plunger head may be perpendicular to each other.

In various embodiments, the system may further include a valve positioned relative to an end of the channel in the plunger head. The valve may allow for closing the channel in the plunger head when the valve is in a closed position. In some embodiments, the system may include a valve positioned relative to an end of the passage in the reservoir. The valve may allow for closing the passage in the reservoir when the valve is in a closed position.

In various embodiments, the system may further include a structure. The structure may have a chamber connected to the passage. The chamber may allow for collecting fluidic media

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that flows through the passage in the reservoir. Fluidic media may flow through the passage when the channel in the plunger head and the passage in the reservoir are aligned and a pressure difference exists between the interior volume of the reservoir and the passage. The structure may include a membrane configured to expand to increase the volume of the chamber in a case where the chamber sufficiently fills with fluidic media. The membrane may comprise an elastomeric membrane. The system may include one of a hydrophobic filter and a hydrophilic filter. The chamber may be located within the reservoir. In some embodiments, the chamber may be located outside of the reservoir. The system may further include at least one seal member positioned between the plunger head and the reservoir.

A method for equalizing pressure may include, but is not limited to, providing a reservoir having a passage and an interior volume for containing fluidic media, and locating a plunger head having a first surface and a second surface, where the plunger head has a channel connecting the first surface and the second surface, the plunger head is moveable within the reservoir to align the channel in the plunger head and the passage in the reservoir, and when the channel in the plunger head and the passage in the reservoir are aligned and a pressure difference exists between the interior volume of the reservoir and the passage, fluidic media is expelled from the interior volume of the reservoir through the passage.

A system for equalizing pressure may include, but is not limited to, a mating piece, a needle, a reservoir, and at least one valve. The needle may be supported by the mating piece.

The reservoir may have an interior volume for containing fluidic media. The mating piece may be configured to be selectively operatively engaged with and disengaged from the reservoir. The reservoir may have a port for allowing fluidic media to be expelled from the interior volume of the reservoir before the reservoir and the mating piece are operatively engaged. The at least one valve may be positioned relative to an end of the port. The at least one valve may be for closing the port when the mating piece and the reservoir are operatively engaged. The needle may be for piercing the at least one valve and entering the interior volume of the reservoir when the reservoir and the mating piece are operatively engaged. The needle may allow for fluidic media contained in the interior volume of the reservoir to flow through the needle when the needle is in the interior volume of the reservoir.

In various embodiments, the system may further include a structure having a chamber connected to the port of the reservoir. The chamber may allow for collecting fluidic media expelled from the interior volume of the reservoir before the reservoir and the mating piece are operatively engaged. Fluidic media may be expelled from the interior volume of the reservoir before the reservoir and the mating piece are operatively engaged in a case where a pressure difference exists between the reservoir and the chamber. The system may further include a membrane configured to expand to increase the volume of the chamber in a case where the chamber sufficiently fills with fluidic media. The membrane may comprise an elastomeric membrane. The system may include one of a hydrophobic filter and a hydrophilic filter.

In various embodiments, the system may further include a first housing portion and a second housing portion. The first housing portion may be adapted to be carried by a user. The second housing portion may be configured to be selectively operatively engaged with and disengaged from the first housing portion. The reservoir may be supported by one of the first and second housing portions. The mating piece may be supported by the other of the first and second housing portions from the one of the first and second housing portions. The

mating piece and the reservoir may be operatively engaged when the first housing portion and the second housing portion are operatively engaged.

In various embodiments, the at least one valve may have a moveable portion. The moveable portion may be moveable between an open position and a closed position such that the at least one valve is moveable by the mating piece from the open position to the closed position to close the port of the reservoir when the reservoir and the mating piece are operatively engaged. In some embodiments, the moveable portion of the at least one valve may be pierceable by the needle when the reservoir and the mating piece are operatively engaged.

In various embodiments, the at least one valve may be arranged to be held closed by the mating piece to close the port of the reservoir when the reservoir and the mating piece are operatively engaged. In some embodiments, the at least one valve may comprise one of a flapper valve and a loose fitting cap. In other embodiments, the at least one valve may comprise a covering that seals the port of the reservoir. The covering may have an opening. The opening may be for allowing fluidic media to be expelled from the interior volume of the reservoir before the reservoir and the mating piece are operatively engaged. The covering may have a second valve positioned relative to an end of the opening in the covering. The second valve may be arranged to be held closed by the mating piece to close the opening in the covering when the reservoir and the mating piece are operatively engaged. In other embodiments, the needle may be positioned to enter the opening when the reservoir and the mating piece are operatively engaged.

A method for equalizing pressure may include, but is not limited to, providing a mating piece, locating a needle supported by the mating piece, locating a reservoir having an interior volume for containing fluidic media, where the mating piece is configured to be selectively operatively engaged with and disengaged from the reservoir, and the reservoir has a port for allowing fluidic media to be expelled from the interior volume of the reservoir before the reservoir and the mating piece are operatively engaged, and locating at least one valve relative to an end of the port, where the at least one valve allows for closing the port when the mating piece and the reservoir are operatively engaged. The needle allows for piercing the at least one valve and entering the interior volume of the reservoir when the reservoir and the mating piece are operatively engaged. The needle allows for fluidic media contained in the interior volume of the reservoir to flow through the needle when the needle is in the interior volume of the reservoir.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a generalized representation of a system in accordance with an embodiment of the present invention;

FIG. 2 illustrates an example of a system in accordance with an embodiment of the present invention;

FIG. 3 illustrates an example of a delivery device in accordance with an embodiment of the present invention;

FIG. 4 illustrates a delivery device in accordance with an embodiment of the present invention;

FIG. 5A illustrates a durable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 5B illustrates a section view of a durable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 5C illustrates a section view of a durable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 6A illustrates a disposable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 6B illustrates a section view of a disposable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 6C illustrates a section view of a disposable portion of a delivery device in accordance with an embodiment of the present invention;

FIG. 7A illustrates a cross-sectional view of a delivery device in accordance with an embodiment of the present invention;

FIG. 7B illustrates a cross-sectional view of a reservoir assembly in accordance with an embodiment of the present invention;

FIG. 7C illustrates a cross-sectional view of a reservoir assembly connected to a base assembly in accordance with an embodiment of the present invention;

FIG. 8A illustrates a cross-sectional view of a system for equalizing pressure in a first position in accordance with an embodiment of the present invention;

FIG. 8B illustrates a cross-sectional view of a system for equalizing pressure in a second position in accordance with an embodiment of the present invention;

FIG. 8C illustrates a cross-sectional view of a reservoir in accordance with an embodiment of the present invention;

FIG. 9A illustrates a cross-sectional view of a system for equalizing pressure in accordance with an embodiment of the present invention;

FIG. 9B illustrates a cross-sectional view of a system for equalizing pressure in accordance with an embodiment of the present invention;

FIG. 9C illustrates a cross-sectional view of a reservoir in accordance with an embodiment of the present invention;

FIG. 9D illustrates a cross-sectional view of a system for equalizing pressure in accordance with an embodiment of the present invention;

FIG. 10A illustrates a cross-sectional view of a system for equalizing pressure in a first position in accordance with an embodiment of the present invention;

FIG. 10B illustrates a cross-sectional view of a system for equalizing pressure in a second position in accordance with an embodiment of the present invention;

FIG. 10C illustrates a cross-sectional view of a reservoir in accordance with an embodiment of the present invention;

FIG. 11A illustrates a cross-sectional view of a system for equalizing pressure in a first position in accordance with an embodiment of the present invention;

FIG. 11B illustrates a cross-sectional view of a system for equalizing pressure in a second position in accordance with an embodiment of the present invention;

FIG. 12A illustrates a cross-sectional view of a system for equalizing pressure in a first position in accordance with an embodiment of the present invention;

FIG. 12B illustrates a cross-sectional view of a system for equalizing pressure in a second position in accordance with an embodiment of the present invention;

FIG. 12C illustrates a cross-sectional view of a reservoir in accordance with an embodiment of the present invention; and

FIG. 13 illustrates a cross-sectional view of a conventional pump delivery device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates a generalized representation of a system 10 in accordance with an embodiment of the present invention. The system 10 includes a delivery device 12. The system

10 may further include a sensing device **14**, a command control device (CCD) **16**, and a computer **18**. In various embodiments, the delivery device **12** and the sensing device **14** may be secured at desired locations on the body **5** of a patient or user **7**. The locations at which the delivery device **12** and the sensing device **14** are secured to the body **5** of the user **7** in FIG. **1** are provided only as representative, non-limiting, examples.

The delivery device **12** is configured to deliver fluidic media to the body **5** of the user **7**. In various embodiments, fluidic media includes a liquid, a fluid, a gel, or the like. In some embodiments, fluidic media includes a medicine or a drug for treating a disease or a medical condition. For example, fluidic media may include insulin for treating diabetes, or may include a drug for treating pain, cancer, a pulmonary disorder, HIV, or the like. In some embodiments, fluidic media includes a nutritional supplement, a dye, a tracing medium, a saline medium, a hydration medium, or the like.

The sensing device **14** includes a sensor, a monitor, or the like, for providing sensor data or monitor data. In various embodiments, the sensing device **14** may be configured to sense a condition of the user **7**. For example, the sensing device **14** may include electronics and enzymes reactive to a biological condition, such as a blood glucose level, or the like, of the user **7**. In various embodiments, the sensing device **14** may be secured to the body **5** of the user **7** or embedded in the body **5** of the user **7** at a location that is remote from the location at which the delivery device **12** is secured to the body **5** of the user **7**. In various other embodiments, the sensing device **14** may be incorporated within the delivery device **12**.

Each of the delivery device **12**, the sensing device **14**, the CCD **16**, and the computer **18** may include transmitter, receiver, or transceiver electronics that allow for communication with other components of the system **10**. The sensing device **14** may be configured to transmit sensor data or monitor data to the delivery device **12**. The sensing device **14** may also be configured to communicate with the CCD **16**. The delivery device **12** may include electronics and software that are configured to analyze sensor data and to deliver fluidic media to the body **5** of the user **7** based on the sensor data and/or preprogrammed delivery routines.

The CCD **16** and the computer **18** may include electronics and other components configured to perform processing, delivery routine storage, and to control the delivery device **12**. By including control functions in the CCD **16** and/or the computer **18**, the delivery device **12** may be made with more simplified electronics. However, in some embodiments, the delivery device **12** may include all control functions, and may operate without the CCD **16** and the computer **18**. In various embodiments, the CCD **16** may be a portable electronic device. Also, in various embodiments, the delivery device **12** and/or the sensing device **14** may be configured to transmit data to the CCD **16** and/or the computer **18** for display or processing of the data by the CCD **16** and/or the computer **18**. Examples of the types of communications and/or control capabilities, as well as device feature sets and/or program options may be found in the following references: (i) U.S. patent application Ser. No. 10/445,477, filed May 27, 2003, entitled "External Infusion Device with Remote Programming, Bolus Estimator and/or Vibration Alarm Capabilities"; (ii) U.S. patent application Ser. No. 10/429,385, filed May 5, 2003, entitled "Handheld Personal Data Assistant (PDA) with a Medical Device and Method of Using the Same"; and (iii) U.S. patent application Ser. No. 09/813,660, filed Mar. 21,

2001, entitled "Control Tabs for Infusion Devices and Methods of Using the Same", all of which are incorporated herein by reference in their entirety.

FIG. **2** illustrates an example of the system **10** in accordance with an embodiment of the present invention. The system **10** in accordance with the embodiment illustrated in FIG. **2** includes the delivery device **12** and the sensing device **14**. The delivery device **12** in accordance with an embodiment of the present invention includes a disposable housing **20**, a durable housing **30**, and a reservoir **40**. The delivery device **12** may further include an infusion path **50**.

Elements of the delivery device **12** that ordinarily contact the body of a user or that ordinarily contact fluidic media during operation of the delivery device **12** may be considered as a disposable portion of the delivery device **12**. For example, a disposable portion of the delivery device **12** may include the disposable housing **20** and the reservoir **40**. The disposable portion of the delivery device **12** may be recommended for disposal after a specified number of uses.

On the other hand, elements of the delivery device **12** that do not ordinarily contact the body of the user or fluidic media during operation of the delivery device **12** may be considered as a durable portion of the delivery device **12**. For example, a durable portion of the delivery device **12** may include the durable housing **30**, electronics (not shown in FIG. **2**), a drive device having a motor and drive linkage (not shown in FIG. **2**), and the like. Elements of the durable housing portion of the delivery device **12** are typically not contaminated from contact with the user or fluidic media during normal operation of the delivery device **12** and, thus, may be retained for re-use with replaced disposable portions of the delivery device **12**.

In various embodiments, the disposable housing **20** supports the reservoir **40** and has a bottom surface (facing downward and into the page in FIG. **2**) that is configured to secure to the body of a user. An adhesive may be employed at an interface between the bottom surface of the disposable housing **20** and the skin of a user, so as to adhere the disposable housing **20** to the skin of the user. In various embodiments, the adhesive may be provided on the bottom surface of the disposable housing **20**, with a peelable cover layer covering the adhesive material. In this manner, the cover layer may be peeled off to expose the adhesive material, and the adhesive side of the disposable housing **20** may be placed against the skin of the user.

The reservoir **40** is configured for containing or holding fluidic media, such as, but not limited to insulin. In various embodiments, the reservoir **40** includes a hollow interior volume for receiving fluidic media, such as, but not limited to, a cylinder-shaped volume, a tubular-shaped volume, or the like. In some embodiments, the reservoir **40** may be provided as a cartridge or canister for containing fluidic media. In various embodiments, the reservoir **40** is able to be refilled with fluidic media. In further embodiments, the reservoir **40** is pre-filled with fluidic media.

The reservoir **40** may be supported by the disposable housing **20** in any suitable manner. For example, the disposable housing **20** may be provided with projections or struts (not shown), or a trough feature (not shown), for holding the reservoir **40**. In some embodiments, the reservoir **40** may be supported by the disposable housing **20** in a manner that allows the reservoir **40** to be removed from the disposable housing **20** and replaced with another reservoir. Alternatively, or in addition, the reservoir **40** may be secured to the disposable housing **20** by a suitable adhesive, a strap, or other coupling structure.

In various embodiments, the reservoir **40** includes a port **41** for allowing fluidic media to flow into and/or flow out of the

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interior volume of the reservoir **40**. In some embodiments, the infusion path **50** includes a connector **56**, a tube **54**, and a needle apparatus **52**. The connector **56** of the infusion path **50** may be connectable to the port **41** of the reservoir **40**. In various embodiments, the disposable housing **20** is configured with an opening near the port **41** of the reservoir **40** for allowing the connector **56** of the infusion path **50** to be selectively connected to and disconnected from the port **41** of the reservoir **40**.

In various embodiments, the port **41** of the reservoir **40** is covered with or supports a septum (not shown in FIG. 2), such as a self-sealing septum, or the like. The septum may be configured to prevent fluidic media from flowing out of the reservoir **40** through the port **41** when the septum is not pierced. Also, in various embodiments, the connector **56** of the infusion path **50** includes a needle for piercing the septum covering the port **41** of the reservoir **40** so as to allow fluidic media to flow out of the interior volume of the reservoir **40**. Examples of needle/septum connectors can be found in U.S. patent application Ser. No. 10/328,393, filed Dec. 22, 2003, entitled "Reservoir Connector", which is incorporated herein by reference in its entirety. In other alternatives, non-septum connectors such as Luer locks, or the like may be used. In various embodiments, the needle apparatus **52** of the infusion path **50** includes a needle that is able to puncture the skin of a user. Also, in various embodiments, the tube **54** connects the connector **56** with the needle apparatus **52** and is hollow, such that the infusion path **50** is able to provide a path to allow for the delivery of fluidic media from the reservoir **40** to the body of a user.

The durable housing **30** of the delivery device **12** in accordance with various embodiments of the present invention includes a housing shell configured to mate with and secure to the disposable housing **20**. The durable housing **30** and the disposable housing **20** may be provided with correspondingly shaped grooves, notches, tabs, or other suitable features, that allow the two parts to easily connect together, by manually pressing the two housings together, by twist or threaded connection, or other suitable manner of connecting the parts that is well known in the mechanical arts. In various embodiments, the durable housing **30** and the disposable housing **20** may be connected to each other using a twist action. The durable housing **30** and the disposable housing **20** may be configured to be separable from each other when a sufficient force is applied to disconnect the two housings from each other. For example, in some embodiments the disposable housing **20** and the durable housing **30** may be snapped together by friction fitting. In various embodiments, a suitable seal, such as an o-ring seal, may be placed along a peripheral edge of the durable housing **30** and/or the disposable housing **20**, so as to provide a seal against water entering between the durable housing **30** and the disposable housing **20**.

The durable housing **30** of the delivery device **12** may support a drive device (not shown in FIG. 2), including a motor and a drive device linkage portion, for applying a force to fluidic media within the reservoir **40** to force fluidic media out of the reservoir **40** and into an infusion path, such as the infusion path **50**, for delivery to a user. For example, in some embodiments, an electrically driven motor may be mounted within the durable housing **30** with appropriate linkage for operatively coupling the motor to a plunger arm (not shown in FIG. 2) connected to a plunger head (not shown in FIG. 2) that is within the reservoir **40** and to drive the plunger head in a direction to force fluidic media out of the port **41** of the reservoir **40** and to the user. Also, in some embodiments, the motor may be controllable to reverse direction so as to move the plunger arm and the plunger head to cause fluid to be

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drawn into the reservoir **40** from a patient. The motor may be arranged within the durable housing **30** and the reservoir **40** may be correspondingly arranged on the disposable housing **20**, such that the operable engagement of the motor with the plunger head, through the appropriate linkage, occurs automatically upon the user connecting the durable housing **30** with the disposable housing **20** of the delivery device **12**. Further examples of linkage and control structures may be found in U.S. patent application Ser. No. 09/813,660, filed Mar. 21, 2001, entitled "Control Tabs for Infusion Devices and Methods of Using the Same", which is incorporated herein by reference in its entirety.

In various embodiments, the durable housing **30** and the disposable housing **20** may be made of suitably rigid materials that maintain their shape, yet provide sufficient flexibility and resilience to effectively connect together and disconnect, as described above. The material of the disposable housing **20** may be selected for suitable compatibility with skin. For example, the disposable housing **20** and the durable housing **30** of the delivery device **12** may be made of any suitable plastic, metal, composite material, or the like. The disposable housing **20** may be made of the same type of material or a different material relative to the durable housing **30**. In some embodiments, the disposable housing **20** and the durable housing **30** may be manufactured by injection molding or other molding processes, machining processes, or combinations thereof.

For example, the disposable housing **20** may be made of a relatively flexible material, such as a flexible silicone, plastic, rubber, synthetic rubber, or the like. By forming the disposable housing **20** of a material capable of flexing with the skin of a user, a greater level of user comfort may be achieved when the disposable housing **20** is secured to the skin of the user. Also, a flexible disposable housing **20** may result in an increase in site options on the body of the user at which the disposable housing **20** may be secured.

In the embodiment illustrated in FIG. 2, the delivery device **12** is connected to the sensing device **14** through a connection element **16** of the sensing device **14**. The sensing device **14** may include a sensor **15** that includes any suitable biological or environmental sensing device, depending upon a nature of a treatment to be administered by the delivery device **12**. For example, in the context of delivering insulin to a diabetes patient, the sensor **15** may include a blood glucose sensor, or the like.

The sensor **15** may be an external sensor that secures to the skin of a user or, in other embodiments, may be an implantable sensor that is located in an implant site within the body of the user. In further alternatives, the sensor may be included with as a part or along side the infusion cannula and/or needle, such as for example as shown in U.S. patent application Ser. No. 11/149,119, filed Jun. 8, 2005, entitled "Dual Insertion Set", which is incorporated herein by reference in its entirety. In the illustrated example of FIG. 2, the sensor **15** is an external sensor having a disposable needle pad that includes a needle for piercing the skin of the user and enzymes and/or electronics reactive to a biological condition, such as blood glucose level or the like, of the user. In this manner, the delivery device **12** may be provided with sensor data from the sensor **15** secured to the user at a site remote from the location at which the delivery device **12** is secured to the user.

While the embodiment shown in FIG. 2 includes a sensor **15** connected by the connection element **16** for providing sensor data to sensor electronics (not shown in FIG. 2) located within the durable housing **30** of the delivery device **12**, other embodiments may employ a sensor **15** located within the delivery device **12**. Yet other embodiments may employ a

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sensor 15 having a transmitter for communicating sensor data by a wireless communication link with receiver electronics (not shown in FIG. 2) located within the durable housing 30 of the delivery device 12. In various embodiments, a wireless connection between the sensor 15 and the receiver electronics within the durable housing 30 of the delivery device 12 may include a radio frequency (RF) connection, an optical connection, or another suitable wireless communication link. Further embodiments need not employ the sensing device 14 and, instead, may provide fluidic media delivery functions without the use of sensor data.

As described above, by separating disposable elements of the delivery device 12 from durable elements, the disposable elements may be arranged on the disposable housing 20, while durable elements may be arranged within a separable durable housing 30. In this regard, after a prescribed number of uses of the delivery device 12, the disposable housing 20 may be separated from the durable housing 30, so that the disposable housing 20 may be disposed of in a proper manner. The durable housing 30 may then be mated with a new (unused) disposable housing 20 for further delivery operation with a user.

FIG. 3 illustrates an example of the delivery device 12 in accordance with another embodiment of the present invention. The delivery device 12 of the embodiment of FIG. 3 is similar to the delivery device 12 of the embodiment of FIG. 2. While the delivery device 12 in the embodiment illustrated in FIG. 2 provides for the durable housing 30 to cover the reservoir 40, the delivery device 12 in the embodiment of FIG. 3 provides for the durable housing 30 to secure to the disposable housing 20 without covering the reservoir 40. The delivery device 12 of the embodiment illustrated in FIG. 3 includes the disposable housing 20, and the disposable housing 20 in accordance with the embodiment illustrated in FIG. 3 includes a base 21 and a reservoir retaining portion 24. In one embodiment, the base 21 and reservoir retaining portion 24 may be formed as a single, unitary structure.

The base 21 of the disposable housing 20 is configured to be secured to the body of a user. The reservoir retaining portion 24 of the disposable housing 20 is configured to house the reservoir 40. The reservoir retaining portion 24 of the disposable housing 20 may be configured to have an opening to allow for the port 41 of the reservoir 40 to be accessed from outside of the reservoir retaining portion 24 while the reservoir 40 is housed in the reservoir retaining portion 24. The durable housing 30 may be configured to be attachable to and detachable from the base 21 of the disposable housing 20. The delivery device 12 in the embodiment illustrated in FIG. 3 includes a plunger arm 60 that is connected to or that is connectable to a plunger head (not shown in FIG. 3) within the reservoir 40.

FIG. 4 illustrates another view of the delivery device 12 of the embodiment of FIG. 3. The delivery device 12 of the embodiment illustrated in FIG. 4 includes the disposable housing 20, the durable housing 30, and the infusion path 50. The disposable housing 20 in the embodiment of FIG. 4 includes the base 21, the reservoir retaining portion 24, and a peelable cover layer 25. The peelable cover layer 25 may cover an adhesive material on the bottom surface 22 of the base 21. The peelable cover layer 25 may be configured to be peelable by a user to expose the adhesive material on the bottom surface 22 of the base 21. In some embodiments, there may be multiple adhesive layers on the bottom surface 22 of the base 21 that are separated by peelable layers.

The infusion path 50 in accordance with the embodiment of the present invention illustrated in FIG. 4 includes the needle 58 rather than the connector 56, the tube 54, and the

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needle apparatus 52 as shown in the embodiment of FIG. 2. The base 21 of the disposable housing 20 may be provided with an opening or pierceable wall in alignment with a tip of the needle 58, to allow the needle 58 to pass through the base 21 and into the skin of a user under the base 21, when extended. In this manner, the needle 58 may be used to pierce the skin of the user and deliver fluidic media to the user.

Alternatively, the needle 58 may be extended through a hollow cannula (not shown in FIG. 4), such that upon piercing the skin of the user with the needle 58, an end of the hollow cannula is guided through the skin of the user by the needle 58. Thereafter, the needle 58 may be removed, leaving the hollow cannula in place, with one end of the cannula located within the body of the user and the other end of the cannula in fluid flow connection with fluidic media within the reservoir 40, to convey pumped infusion media from the reservoir 40 to the body of the user.

FIG. 5A illustrates a durable portion 8 of the delivery device 12 (refer to FIG. 3) in accordance with an embodiment of the present invention. FIG. 5B illustrates a section view of the durable portion 8 in accordance with an embodiment of the present invention. FIG. 5C illustrates another section view of the durable portion 8 in accordance with an embodiment of the present invention. With reference to FIGS. 5A, 5B, and 5C, in various embodiments, the durable portion 8 includes the durable housing 30, and a drive device 80. The drive device 80 includes a motor 84 and a drive device linkage portion 82. In various embodiments, the durable housing 30 may include an interior volume for housing the motor 84, the drive device linkage portion 82, other electronic circuitry, and a power source (not shown in FIGS. 5A, 5B, and 5C). Also, in various embodiments, the durable housing 30 is configured with an opening 32 for receiving a plunger arm 60 (refer to FIG. 3). Also, in various embodiments, the durable housing 30 may include one or more connection members 34, such as tabs, insertion holes, or the like, for connecting with the base 21 of the disposable housing 20 (refer to FIG. 3).

FIG. 6A illustrates a disposable portion 9 of the delivery device 12 (refer to FIG. 3) in accordance with an embodiment of the present invention. FIG. 6B illustrates a section view of the disposable portion 9 in accordance with an embodiment of the present invention. FIG. 6C illustrates another section view of the disposable portion 9 in accordance with an embodiment of the present invention. With reference to FIGS. 6A, 6B, and 6C, in various embodiments, the disposable portion 9 includes the disposable housing 20, the reservoir 40, the plunger arm 60, and a plunger head 70. In some embodiments, the disposable housing 20 includes the base 21 and the reservoir retaining portion 24. In various embodiments, the base 21 includes a top surface 23 having one or more connection members 26, such as tabs, grooves, or the like, for allowing connections with the one or more connection members 34 of embodiments of the durable housing 30 (refer to FIG. 5B).

In various embodiments, the reservoir 40 is housed within the reservoir retaining portion 24 of the disposable housing 20, and the reservoir 40 is configured to hold fluidic media. Also, in various embodiments, the plunger head 70 is disposed at least partially within the reservoir 40 and is moveable within the reservoir 40 to allow fluidic media to fill into the reservoir 40 and to force fluidic media out of the reservoir 40. In some embodiments, the plunger arm 60 is connected to or is connectable to the plunger head 70. Also, in some embodiments, a portion of the plunger arm 60 extends to outside of the reservoir retaining portion 24 of the disposable housing 20. In various embodiments, the plunger arm 60 has a mating portion for mating with the drive device linkage portion 82 of the drive device 80 (refer to FIG. 5C). With reference to FIGS.

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5C and 6C, in some embodiments, the durable housing 30 may be snap fitted onto the disposable housing 20, whereupon the drive device linkage portion 82 automatically engages the mating portion of the plunger arm 60.

When the durable housing 30 and the disposable housing 20 are fitted together with the drive device linkage portion 82 engaging or mating with the plunger arm 60, the motor 84 may be controlled to drive the drive device linkage portion 82 and, thus, move the plunger arm 60 to cause the plunger head 70 to move within the reservoir 40. When the interior volume of the reservoir 40 is filled with fluidic media and an infusion path is provided from the reservoir 40 to the body of a user, the plunger head 70 may be moved within the reservoir 40 to force fluidic media from the reservoir 40 and into the infusion path, so as to deliver fluidic media to the body of the user.

In various embodiments, once the reservoir 40 has been sufficiently emptied or otherwise requires replacement, a user may simply remove the durable housing 30 from the disposable housing 20, and replace the disposable portion 9, including the reservoir 40, with a new disposable portion having a new reservoir. The durable housing 30 may be connected to the new disposable housing of the new disposable portion, and the delivery device including the new disposable portion may be secured to the skin of a user. In various other embodiments, rather than replacing the entire disposable portion 9 every time the reservoir 40 is emptied, the reservoir 40 may be refilled with fluidic media. In some embodiments, the reservoir 40 may be refilled while remaining within the reservoir retaining portion 24 (refer to FIG. 6B) of the disposable housing 20. Also, in various embodiments, the reservoir 40 may be replaced with a new reservoir (not shown), while the disposable housing 20 may be re-used with the new reservoir. In such embodiments, the new reservoir may be inserted into the disposable portion 9.

With reference to FIGS. 3, 5A, 6B, and 6C, in various embodiments, the delivery device 12 includes reservoir status circuitry (not shown), and the reservoir 40 includes reservoir circuitry (not shown). In various embodiments, the reservoir circuitry stores information such as, but not limited to, at least one of (i) an identification string identifying the reservoir 40; (ii) a manufacturer of the reservoir 40; (iii) contents of the reservoir 40; and (iv) an amount of contents in the reservoir 40. In some embodiments, the delivery device 12 includes the reservoir status circuitry (not shown), and the reservoir status circuitry is configured to read data from the reservoir circuitry when the reservoir 40 is inserted into the disposable portion 9.

In various embodiments, the reservoir status circuitry is further configured to store data to the reservoir circuitry after at least some of the contents of the reservoir 40 have been transferred out of the reservoir 40, so as to update information in the reservoir circuitry related to an amount of contents still remaining in the reservoir 40. In some embodiments, the reservoir status circuitry is configured to store data to the reservoir circuitry, so as to update information in the reservoir circuitry related to an amount of contents still remaining in the reservoir 40, when the reservoir 40 is inserted into the disposable portion 9. In some embodiments, the delivery device 12 includes the reservoir status circuitry (not shown) and the reservoir 40 includes the reservoir circuitry (not shown), and the reservoir status circuitry selectively inhibits use of the delivery device 12 or selectively provides a warning signal based on information read by the reservoir status circuitry from the reservoir circuitry.

FIG. 7A illustrates a cross-sectional view of a delivery device 100 in accordance with an embodiment of the present invention. The delivery device 100 may include, but not limited to, a reservoir assembly 102 and a base assembly 104.

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The reservoir assembly 102 and the base assembly 104 may be configured to be connected to and disconnected from one another by the user. The base assembly 104, which may be adapted to be carried by the user, may include a fluid path 190 for receiving fluidic media from the reservoir assembly 102. The base assembly 104 may also include a subcutaneous cannula 194 or catheter having a needle path 192 to allow an injection needle (not shown) to pierce the skin of the user and allow fluidic media to flow into the body of a patient.

FIG. 7B illustrates a cross-sectional view of the reservoir assembly 102 in accordance with an embodiment of the present invention. With reference to FIGS. 7A and 7B, the reservoir assembly 102 may include a reservoir 110 and a first structure 170 having a chamber 175. The reservoir 110 may contain fluidic media, such as, but not limited to, insulin or the like. The first structure 170 may include a needle 130 and a pierceable member 140. The needle 130 may be connected to the reservoir 110 for allowing fluidic media contained in the reservoir 110 to flow through the needle 130 when the needle 130 is connected to the reservoir 110. The needle 130 may have a longitudinal dimension and a central axis along the longitudinal dimension of the needle 130.

The pierceable member 140 may be located within the chamber 175. The pierceable member 140 may be moveable within the chamber 175 along the longitudinal dimension of the needle 130. The pierceable member 140 may have an interior volume 172 for containing fluidic media expelled from the reservoir 110 before the pierceable member 140 is pierced by the needle 130. In some embodiments of the present invention, the interior volume 172 of the pierceable member 140 may be for containing fluidic media that flows through the needle 130 from the reservoir 110 before the pierceable member 140 is pierced by the needle 130.

In some embodiments of the present invention, the pierceable member 140 may have a cross-section that is U-shaped. In some embodiments of the present invention, the pierceable member 140 may be made of a resealable material. Thus when the user disconnects the reservoir assembly 102 from the base assembly 104, for example to replace an empty reservoir with a new reservoir, the needle 130 is retracted or otherwise removed from the pierceable member 140 and the pierceable member 140 is resealed. As a result, fluidic media contained in the interior volume 172 of the pierceable member 140 may continue to be contained within the interior volume 172 of the pierceable member 140. Once the new reservoir is installed, the interior volume 172 of the pierceable member 140 may be used to contain fluidic media expelled from the new reservoir before the needle 130 again pierces the pierceable member 140.

Fluidic media may be expelled from the reservoir 110 before the pierceable member 140 is pierced by the needle 130 when a pressure difference exists between the reservoir 110 and the chamber 175. This may be due to an external influence such as an altitude or a temperature change or imperfect alignment of a plunger shaft 725 (refer to FIG. 13) and a driveshaft 772 (refer to FIG. 13). In such a case, fluidic media may flow or bolus from the reservoir 110 into the interior volume 172 of the pierceable member 140 until pressure in the reservoir 110 has been sufficiently equalized relative to pressure in the chamber 175. Thus, preventing the user from inadvertently being administered fluidic media, which could harm the user. Once pressure has been sufficiently equalized, fluidic media may be inhibited from flowing through the needle 130 until directed by the delivery device, for example, to satisfy the need of the user. In some embodiments, fluidic media may be expelled from the reservoir 110 before the pierceable member 140 is pierced by the needle

130 in a case where a pressure difference exists between the reservoir 110 and the interior volume 172 of the pierceable member 140.

The pierceable member 140 may have a first end 141 and a second end 142 on an opposite side of the pierceable member 140 from the first end 141. The pierceable member 140 may be positioned in the chamber 175 relative to the needle 130 so that the needle 130 can pierce the pierceable member 140 when the user connects the reservoir assembly 102 with the base assembly 104. Connecting the reservoir assembly 102 with the base assembly 104 may cause the base assembly 104 to push against the first end 141 of the pierceable member 140. As a result, the pierceable member 140 is pushed against the needle 130 causing the needle 130 to pierce through the pierceable member 140. The needle 130 may be positioned to pierce through the pierceable member 140 and enter the fluid path 190 of the base assembly 104 when the user connects the reservoir assembly 102 with the base assembly 104. In some embodiments, an end of the needle 130 may be located at least substantially within the interior volume 172 of the pierceable member 140 before the needle 130 pierces the pierceable member 140. This may help ensure that fluidic media that flows through the needle 130 before piercing the pierceable member 140 is collected in the interior volume 172 of the pierceable member 140.

In some embodiments of the present invention, the chamber 175 may include a first chamber 174. The first chamber 174 may be adjacent to the second end 142 of the pierceable member 140. In other embodiments of the present invention, the first chamber 174 may be located between the pierceable member 140 and the reservoir 110. The first chamber 174 may contain fluidic media that flows out, or otherwise escapes, from the interior volume 172 of the pierceable member 140. For example, this could occur in a case where a volume of fluidic media expelled from the reservoir 110 exceeds a capacity of the interior volume 172 of the pierceable member 140. The excess fluidic media could then flow into the first chamber 174 and be contained therein. As a further example, fluidic media could escape from the interior volume 172 of the pierceable member 140 in a case where fluidic media enters the interior volume 172 too quickly causing fluidic media to flow out of the interior volume 172 into the first chamber 174.

In further embodiments of the present invention, the chamber 175 may include a second chamber 176. The second chamber 176 may be located on an opposite side of the pierceable member 140 from the first chamber 174, such as adjacent to the first end 141 of the pierceable member 140. The pierceable member 140 may be located between the first chamber 174 and the second chamber 176. The second chamber 176 may contain fluidic media that flows out, or otherwise escapes, from the first chamber 174. For example, this could occur in a case where the first chamber 174 fills with fluidic media. The excess fluidic media could then flow between the pierceable member 140 and the structure 170 into the second chamber 176. As a further example, fluidic media could escape from the first chamber 174 in a case where fluidic media enters the first chamber 174 too quickly causing fluidic media to flow out of the first chamber 174 into the second chamber 176. In yet further embodiments of the present invention, the pierceable member 140 may include a seal member 144 around the pierceable member 140. The seal member 144, for example, may aid in inhibiting fluidic media in the second chamber 176 from flowing back into the first chamber 174. In some embodiments, the seal member 144 may be an annular ring that encircles the pierceable member 140.

In yet further embodiments of the present invention, the structure 170 may include an opening 171 in flow communication with the chamber 175. The opening 171 may be for purging fluidic media that flows out, or otherwise escapes, from the interior volume 172 of the pierceable member 140. For example, this could occur in a case where a volume of fluidic media expelled from the reservoir 110 exceeds the capacity of the interior volume 172 of the pierceable member 140. The excess fluidic media may then flow into the chamber 175 and flow out the opening 171 of the structure 170.

In some embodiments of the present invention, the pierceable member 160 may include a membrane wall 152, which may comprise an elastomeric material, or the like. The membrane wall 152 may be configured to expand 152' to increase the volume of the interior volume 172 of the pierceable member 140 in a case where the interior volume 172 of the pierceable member 140 sufficiently fills with fluidic media. This may be useful in a case where the interior volume 172 of the pierceable member 140 is not sufficiently large enough to contain fluidic media expelled from the reservoir 110. The membrane wall 152 may be for inhibiting fluidic media contained in the interior volume 172 of the pierceable member 140 from flowing out of or otherwise escaping from the interior volume 172 of the pierceable member 140. The membrane wall 152 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material.

With reference to FIGS. 7B and 7C, in some embodiments of the present invention, the reservoir assembly 102 may include a bias member 160. The bias member 160 may be arranged to impart a bias force on the pierceable member 140 as, for instance, the base assembly 104 is pushed against the first end 141 of the pierceable member 140 when the user connects the reservoir assembly 102 with the base assembly 104. As a result, the pierceable member 140 can be moved from a first position 191 to a second position 191'. Additionally, the pierceable member 140 may be moved to various positions between the first position 191 and the second position 191', as well as positions beyond the second position 191'. In some embodiments of the present invention, the bias member 160 may be, but is not limited to, a spring or the like.

In further embodiments of the present invention, the pierceable member 140 may have a resiliently flexible portion (not shown) for providing a bias force on the pierceable member 140. In various embodiments, the bias function may be integral to the pierceable member 140, a function of the resiliently flexible portion (not shown), which may be made of a material such as rubber, or the like. The flexible portion (not shown) may, for example, compress allowing the pierceable member 140 to move within the chamber 175 from the first position 191 to the second position 191' when the user connects the base assembly 104 with the reservoir assembly 102 and uncompress when the user disconnects the base assembly 104 and the reservoir assembly 102 returning the pierceable member 140 to the first position 191.

In alternative embodiments, the needle 130 may be supported by the base assembly 104 and positioned to pierce the pierceable member 140 and enter the reservoir 110. The interior volume 172 of the pierceable member 140 may contain fluidic media expelled from the reservoir 110 before the pierceable member 140 is pierced by the needle 130.

In some embodiments of the present invention, the interior volume 172 of the pierceable member 140 may be curved concavely relative to the central axis of the needle 130. This may increase the capacity of the interior volume 172 of the pierceable member 140 to hold more fluidic media. Furthermore, this may allow more fluidic media to be contained

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within the interior volume 172 of the pierceable member 140 when the reservoir assembly 102 is orientated on its side, for example, when the central axis of the needle 130 is parallel to an infusion site (not shown) as may be a case in FIGS. 7A-7C. In further embodiments of the present invention, the system 100 may include a seal member, such as an o-ring 150 or the like located between the structure 170 and the pierceable member 140 to facilitate movement of the pierceable member 140 within the chamber 175. In some embodiments, the o-ring 150 may substantially prevent fluidic media from flowing between the pierceable member 140 and the structure 170.

FIG. 7C illustrates a cross-sectional view of the reservoir assembly 102 connected to the base assembly 104 in accordance with an embodiment of the present invention. Once pressure in the reservoir 110 has been sufficiently equalized, the user may connect the reservoir assembly 102 with the base assembly 104. When the user connects the reservoir assembly 102 and the base assembly 104, the base assembly 104 is pushed against the first end 141 of the pierceable member 140. This forces the pierceable member 140 against the bias member 160 and moves the pierceable member 140 from the first position 191 (refer to FIG. 7B) to the second position 191' causing the needle 130 to pierce through the pierceable member 140 and enter the fluid path 190 of the base assembly 104. As a result, fluidic media can flow from the reservoir 110 through the needle 130 into the fluid path 190 and into the user by way of the needle path 192 and cannula 194 (refer to FIG. 7A) as required by the user.

Fluidic media expelled from the reservoir 110 and collected in the interior volume 172 of the pierceable member 140 before the needle 130 pierces the pierceable member 140 may remain in the interior volume 172 of the pierceable member 140. In other embodiments, fluidic media expelled from the reservoir 110 before the needle 130 pierces the pierceable member 140 may remain in at least one of the interior volume 172 of the pierceable member 140, the first chamber 174, or the second chamber 176.

FIG. 8A illustrates a cross-sectional view of a system 200 for equalizing pressure in a first position in accordance with an embodiment of the present invention. The system 200 may include, but is not limited to, a reservoir assembly 202 and a base assembly 204. The reservoir assembly 202 may include a reservoir 210 having a port 212 and a septum 214, a plug 240, and a structure 255 having a chamber 250. The base assembly 204, which may be adapted to be carried by the user, may include a needle 230. The needle 230 may be for piercing the septum 214 of the reservoir 210 when the user connects the base assembly 204 with the reservoir assembly 202. The needle 230 may be for allowing fluidic media contained in the reservoir 210 to flow through the needle 230 into the base assembly 204 when the needle 230 is connected to the reservoir 210 when, for example, the needle 230 pierces the septum 214 and enters the reservoir 210.

The reservoir 210 may have an interior volume 215 for containing fluidic media, such as, but not limited to, insulin. The port 212 of the reservoir 210 may be for allowing fluidic media to be expelled from the reservoir 210 in a case where a pressure difference exists between the interior volume 215 of the reservoir 210 and the chamber 250. As discussed, this could be due, but is not limited to, an external influence such as an altitude or a temperature change or imperfect alignment of a plunger shaft 225 and a driveshaft 272 when the reservoir 210 is installed into the delivery device.

The plug 240 may be positioned relatively offset to the port 212 of the reservoir 210. The plug 240 may be for closing the port 212 of the reservoir 210 when the plug 240 is in a closed position. For example, when the user connects the reservoir

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assembly 202 and the base assembly together 204, the base assembly 204 forces the plug 240 into or over the port 212 of the reservoir 210 to close the port 212, thus preventing fluidic media in the interior volume 215 of the reservoir 210 from flowing out the port 212 of the reservoir 210. The plug 240 may be, but is not limited to, a flapper valve, a disc valve, or the like.

The chamber 250 of the structure 255 may be connected to the reservoir 210. The chamber 250 may be for collecting fluidic media expelled from the interior volume 215 of the reservoir 210 in a case where a pressure difference exists between the interior volume 215 of the reservoir 210 and the chamber 250. As shown in FIG. 8A, the plug 240 initially may be in an open position so that the port 212 is at least partially unobstructed so that fluidic media can flow freely or bolus through the port 212 into the chamber 250 in a case where a pressure difference exists between the interior volume 215 of the reservoir 210 and the chamber 250. Fluidic media may flow through the port 212 until pressure within the interior volume 215 of the reservoir 210 has been sufficiently equalized relative to pressure in the chamber 250. In other embodiments, the plug 240 may be located at least partially in or over the port 212 and may be positioned to be forced away from the port 212 by the expelled fluidic media. Once pressure in the interior volume 215 of the reservoir 210 has been sufficiently equalized, the reservoir assembly 202 may be connected with the base assembly 204.

The structure 255 having the chamber 250 may be located outside of the reservoir 210. For example, the chamber 250 may be adjacent to the reservoir 210. In other embodiments, such as the embodiment illustrated in FIG. 8C, a structure 256 having a chamber 251 may be located within the reservoir 210. With reference to FIG. 8A, in further embodiments of the present invention, the structure 255 may include a membrane wall 252, which may comprise an elastomeric material, or the like. The membrane wall 252 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material. The membrane wall 252 may be configured to expand (252' in FIG. 8B) to increase the volume of the chamber 250 in a case where the chamber 250 sufficiently fills with fluidic media. In yet further embodiments of the present invention, the structure 255 may have an opening (not shown) in communication with the chamber 250 for purging fluidic media collected in the interior volume of the chamber 250. This may be useful in a case where the interior volume of the chamber 250 is not sufficiently large enough to contain fluidic media expelled from the interior volume 215 of the reservoir 210.

FIG. 8B illustrates a cross-sectional view of the system 200 for relieving pressure in a second position in accordance with an embodiment of the present invention. Once pressure in the interior volume 215 of the reservoir 210 has been sufficiently equalized, the user may place the system 200 in the second position by connecting the reservoir assembly 202 with the base assembly 204. In the second position of the system 200, the plug 240 may be in a closed position so that the port 212 of the reservoir 210 is substantially closed, such that fluidic media in the interior volume 215 of the reservoir 210 can no longer flow into the chamber 250. The port 212 may be closed by the plug 240 when the user connects the reservoir assembly 202 with the base assembly 204. In such a case, the base assembly 204 pushes against the plug 240 of the reservoir assembly 202 and forces the plug 240 to enter, or otherwise cover, the port 212 of the reservoir 210 of the reservoir assembly 202. The plug 240 may be held in or against the port 212 by the base assembly 204. The plug 240 may cover the port 212 of the reservoir 210, and fluidic media contained in the

chamber **250** may remain isolated from fluidic media contained in the interior volume **215** of the reservoir **210**. In some embodiments of the present invention, the base assembly **204** and the reservoir assembly **202** are not connected until pressure in the interior volume **215** of the reservoir **210** has been equalized with respect to pressure in the chamber **250**.

According to the embodiment illustrated in FIG. **8B**, when the user connects the reservoir assembly **202** and the base assembly **204** together, the needle **230**, which may be supported by the base assembly **204**, pierces the septum **214** of the reservoir **210** and enters the reservoir **210**. As a result, fluidic media contained in the interior volume **215** of the reservoir **210** can flow through the needle **230** into the base assembly **204** and ultimately to the user. For example with reference to FIGS. **7A** and **8B**, fluidic media in the interior volume **215** of the reservoir **210** may flow through the needle **230** into a fluid path **190** into the needle passage **192** and then the cannula **194** and into the user. In other embodiments of the present invention, the needle **230** may be positioned to pierce the plug **240** and enter the reservoir **210**. Thus establishing a path for fluidic media in the interior volume **215** of the reservoir **210** to flow through the needle **230** into the base assembly **204** and then to the user. In further embodiments, the reservoir **210** may have a second port (not shown) for delivering fluidic media contained in the interior volume **215** of the reservoir **210** to the base assembly **204** while the reservoir assembly **202** and the base assembly **204** are connected.

FIG. **9A** illustrates a cross-sectional view of a system **300** for equalizing pressure in accordance with an embodiment of the present invention. The system **300** may include, but is not limited to, a reservoir **310** and a plunger head **320**. The reservoir **310** may have an interior volume **315** for containing fluidic media, such as, but not limited to, insulin. The reservoir **310** may have a passage **340** for allowing fluidic media to be expelled from the interior volume **315** of the reservoir **310** in a case where a pressure difference exists between the interior volume **315** of the reservoir **310** and the passage **340**.

The plunger head **320** may be located within the reservoir **310** and may be moveable within the reservoir **310** to expand or contract the interior volume **315** of the reservoir **310**. The plunger head **320** may be connected to a plunger shaft **325**. The plunger shaft **325** may comprise, for example, a half-nut, a quarter-nut, a U-shaped nut, or the like, that is able to engage a driveshaft **372** mechanically coupled to a motor (not shown). The driveshaft **372** may be, for example, a partial screw or the like. The plunger head **320** may have a first surface **321** and a second surface **322** connected by a channel **330**. The plunger head **320** may be moveable within the reservoir **310** to align the channel **330** with the passage **340**. When the channel **330** and the passage **340** are aligned and a pressure difference exists between the interior volume **315** of the reservoir **310** and the passage **340**, fluidic media may be expelled from the interior volume **315** of the reservoir **310** through the passage **340**.

In some embodiments of the present invention, the reservoir **310** may have a second interior volume **317**. The interior volume **315** of the reservoir **310** may allow for containing fluidic media. The plunger head **320** may be located between the interior volume **315** of the reservoir **310** and the second interior volume **317** of the reservoir **310**. As the plunger head **320** is advanced within the reservoir **310**, the interior volume **315** may be decreased, while the second interior volume **317** may be increased. The first surface **321** of the plunger head **320** may be in contact with fluidic media when fluidic media is in the interior volume **315** of the reservoir **310**.

In some embodiments of the present invention, the first surface **321** of the plunger head **320** may be perpendicular to

the second surface **322** of the plunger head **320**. For example, in the embodiment illustrated in FIG. **9A**, when the channel **330** and the passage **340** are aligned and a pressure difference exists between the interior volume **315** of the reservoir **310** and the passage **340**, fluidic media expelled from the interior volume **315** of the reservoir **310** may flow into the channel **330** and flow out the passage **340** located on a side of the reservoir **310**. In further embodiments of the present invention, the system **300** may include a seal member (not shown), such as an o-ring or the like, located between the plunger head **320** and the reservoir **310** to facilitate movement of the plunger head **320** within the reservoir **310** and to prevent from fluidic media from flowing between the plunger head **320** and the reservoir **310**.

The plunger head **320** may be moveable within the reservoir **310** from a first position **390** to a second position **390'** (refer to FIG. **9B**). In some embodiments, when the plunger head **320** is in the first position **390**, the channel **330** and the passage **340** are aligned to establish a flow path from the interior volume **315** of the reservoir **310** through the channel **330** of the plunger head **320** to the passage **340** of the reservoir **310**. In a case where the channel **330** and the passage **340** are aligned and a pressure difference exists between the interior volume **315** of the reservoir **310** and the passage **340**, fluidic media in the interior volume **315** of the reservoir **310** can flow freely or bolus through the channel **330** into the passage **340** until pressure in the interior volume **315** of the reservoir **310** is sufficiently equalized with respect to pressure in the passage **340**. In the second position **390'** (refer to FIG. **7B**), the passage **340** and the chamber **330** are disaligned (i.e., no longer aligned) so that fluidic media can no longer flow from the interior volume **315** of the reservoir **310** through the passage **340**.

In some embodiments of the present invention, such as the embodiment shown in FIG. **9D**, the system **300** may include a reservoir assembly **302** and a base assembly **304**. The reservoir assembly **302** may support the reservoir **310**. The reservoir assembly **302** can be removably attachable to the base assembly **304**. With reference to FIGS. **9A** and **9B**, the plunger head **320** may be advanceable within the reservoir **310** from the first position **390**, where the passage **340** and the channel **330** are aligned, to the second position **390'**, where the passage **340** and the channel **330** are disaligned, before the user connects the base assembly **304** to the reservoir assembly **302**. The plunger head **320** may be advanced, for example, manually by the user, or by a motor (not shown) attached to the driveshaft **372**. In such an embodiment, the reservoir **310**, having the plunger head **320** in the second position **390'**, would be ready to administer fluidic media safely to the user as needed. Moreover, because fluidic media can no longer flow into the passage **340**, fluidic media may not be wasted when the plunger head **320** is advanced from the second position **390'** to another position.

In some embodiments of the present invention, the reservoir **310** may further include a structure **355** having a chamber **350**. The chamber **350** of the structure **355** may be connected to the passage **340**. The chamber **350** may be for collecting fluidic media that flows through the passage **340**. Fluidic media may flow through the passage **340** when the channel **330** and the passage **340** are aligned and a pressure difference exists between the interior volume **315** of the reservoir **310** and the passage **340**. The structure **355** having the chamber **350** may be located outside of the reservoir **310**, for example, the chamber **350** may be adjacent to the reservoir **310**. In other embodiments of the present invention, such as the embodiment illustrated in FIG. **9C**, a structure **356** having a chamber **351** may be located within the reservoir **310**.

In further embodiments of the present invention, such as the embodiments illustrated in FIGS. 9A and 9B, the structure 355 may include a membrane wall 352, which may comprise an elastomeric material, or the like. The membrane wall 352 may be configured to expand 352' to increase the volume of the chamber 350 in a case where the chamber 350 sufficiently fills with fluidic media. This may be useful in a case where the chamber 350 is not sufficiently large enough to contain fluidic media expelled from the reservoir 310. The membrane wall 352 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material.

In some embodiments of the present invention, a valve 335 may be positioned at an end of the channel 330. The valve 335 may be, but is not limited to, a flapper valve or the like. The valve 335 may be moveable between an open position and a closed position. The valve 335 may be for closing the channel 330 when the valve 335 is in the closed position. The valve 335 may be in the closed position after the plunger head 320 is advanced from the first position 390 to the second position 390' due to an abutting side 311 of the reservoir 310 that may prevent the valve 335 from opening. As a result, fluidic media in the interior volume 315 of the reservoir 310 may be prevented from flowing out the channel 330. In some embodiments, the valve 335 may be in the closed position while the plunger head 320 is in the first position 390 in a case where pressure in the interior volume 315 of the reservoir 310 is relatively equal to pressure in the passage 340, such as after pressure has been equalized or if pressure did not have to be equalized.

In some embodiments of the present invention, a valve 345 may be positioned at an end of the passage 340. The valve 345 may be, but not limited to, a flapper valve or the like. The valve 345 may be moveable between an open position and a closed position. The valve 345 may be for closing the passage 340 when the valve 345 is in the closed position. The valve 345 may be in the closed position after the plunger head 320 is advanced from the first position 390 to the second position 390'. As a result, fluidic media expelled through the passage 340, while the plunger head 320 was in the first position 390, may be prevented from flowing back into the second interior volume 317 of the reservoir 310. This may be desirable because it may keep the reservoir 310 and the delivery device relatively clean and sanitary. In some embodiments, the valve 345 may be in the closed position while the plunger head 320 is in the first position 390 in a case where pressure in the interior volume 315 of the reservoir 310 is relatively equal to pressure in the passage 340, such as after pressure has been equalized or if pressure did not have to be equalized.

FIG. 9B illustrates a cross-sectional view of the system 300 in accordance with an embodiment of the present invention. Once pressure in the interior volume 315 of the reservoir 310 has been sufficiently equalized with respect to pressure in the passage 340, the plunger head 320 may be sufficiently advanced within the reservoir 310 from the first position 390 (refer to FIG. 9A) to the second position 390'. As a result, the passage 340 and the channel 330 of the plunger head 320 are disaligned (i.e., no longer aligned) so that fluidic media in the interior volume 315 of the reservoir 310 may no longer flow into the passage 340. Accordingly, fluidic media that flows from the interior volume 315 of the reservoir 310 into the channel 330 may be prevented from flowing into the passage 340 or otherwise out of the reservoir 310 by the abutting side 311 of the reservoir 310. In addition, fluidic media expelled through the passage 340 may be isolated from fluidic media

contained in the interior volume 315 of the reservoir 310. The reservoir 310 may now be ready to provide fluidic media to the user.

In yet further embodiments, the plunger head 320 need not be advanced from the first position 390 (refer to FIG. 9A) to the second position 390' after pressure in the interior volume 315 of the reservoir 310 has been equalized with respect to pressure in the passage 340. In such an embodiment, the reservoir 310 may be ready to provide fluidic media to the user. For example, when the plunger head 320 is advanced from the first position 390 (refer to FIG. 9A) to satisfy a need of the user, the advancement of the plunger head 320 may be sufficient to disalign the channel 330 and the passage 340 so that the interior volume 315 of the reservoir 310 is no longer in flow communication with the passage 340.

In some embodiments, such as the embodiment illustrated in FIG. 9D, the base assembly 304 may include a needle 380 and a mating piece 370. The needle 380 may be for piercing a septum 314 of the reservoir 310 when the user connects the base assembly 304 with the reservoir assembly 302. The needle 380 may be for allowing fluidic media contained in the interior volume 315 of the reservoir 310 to flow through the needle 380 into the base assembly 304 when the needle 380 is connected to the reservoir 310 when, for example, the needle 380 pierces the septum 314 and enters the interior volume 315 of the reservoir 310. The mating piece 370 may be for covering or blocking the passage 340 when the base assembly 302 and the reservoir assembly 304 are connected so that fluidic media in the interior volume 315 of the reservoir 310 cannot flow out the passage 340 while the reservoir assembly 302 and the base assembly 304 are connected.

FIG. 10A illustrates a cross-sectional view of a system 400 for equalizing pressure in a first position in accordance with an embodiment of the present invention. The system 400 may include, but is not limited to, a reservoir assembly 402 and a base assembly 404. The reservoir assembly 402 may include a reservoir 410 having a port 412 and a flapper valve 440. The base assembly 404 may include a needle 430 and a mating piece 435. The reservoir 410 may have an interior volume 415 for containing fluidic media, such as, but not limited to, insulin. The port 412 may be an outlet for expelling fluidic media from the interior volume 415 of the reservoir 410 before the mating piece 435 and the reservoir 410 are operatively engaged. The mating piece 435 and the reservoir 410 may be operatively engaged when the user connects the reservoir assembly 402 with the base assembly 404.

The flapper valve 440 may be located on the port 412 of the reservoir 410. The flapper valve 440 may be pierceable by the needle 430. The needle 430 may be supported by the mating piece 435 and positioned to pierce the flapper valve 440 when the user connects the reservoir assembly 402 with the base assembly 404 allowing the needle 430 to enter the interior volume 415 of the reservoir 410 to establish a fluid path between the reservoir assembly 402 and the base assembly 404. The flapper valve 440 may be held against the port 412 by the mating piece 435, thus closing the port 412 when the user connects the reservoir assembly 402 with the base assembly 404.

In some embodiments of the present invention, the system 400 may further include a structure 455 having a chamber 450. The chamber 450 of the structure 455 may be connected to the port 412 of the reservoir 410. In other embodiments, the chamber 450 may be connectable to or otherwise in flow communication with the interior volume 415 of the reservoir 410. For example, when the flapper valve 440 is opened to expel fluidic media, a fluid path may be established between the interior volume 415 of the reservoir 410 and the chamber

450. The chamber 450 may have an interior volume for collecting fluidic media expelled through the port 412 from the interior volume 415 of the reservoir 410 before the mating piece 435 and the reservoir 410 are connected or otherwise operatively engaged. Fluidic media may be expelled from the reservoir 410 before the mating piece 435 and the reservoir 410 are operatively engaged in a case where a pressure difference exists between the interior volume 415 of the reservoir 410 and the chamber 450. The structure 455 having the chamber 450 may be located outside of the reservoir 410. For example, the chamber 450 may be adjacent to the reservoir 410. In some embodiments of the present invention, such as the embodiment illustrated in FIG. 10C, a structure 456 having a chamber 451 may be located within the reservoir 410.

As shown in FIG. 10A, the port 412 of the reservoir 410 may be initially in an open position, such that fluidic media expelled from the reservoir 410 to equalize pressure within the interior volume 415 of the reservoir 410, can flow freely or bolus through the port 412. The expelled fluidic media may force the flapper valve 440 to open and flow out of the interior volume 415 of the reservoir 410 until pressure within the interior volume 415 of the reservoir 410 has been equalized with respect to pressure in the chamber 450.

In some embodiments of the present invention, the structure 455 may include a membrane wall 452, which may comprise an elastomeric material, or the like. The membrane wall 452 may be configured to expand (452' in FIG. 10B) outwardly to increase the interior volume of the chamber 450 in a case where the chamber 450 sufficiently fills with fluidic media. The membrane wall 452 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material. In yet further embodiments of the present invention, the structure 455 may have an opening (not shown) for purging fluidic media collected in the interior volume of the chamber 450. This may be useful in a case where the interior volume of the chamber 450 is not sufficiently large enough to contain all of the fluidic media expelled from the interior volume 415 of the reservoir 410.

FIG. 10B illustrates a cross-sectional view of the system 400 for equalizing pressure in a second position in accordance with an embodiment of the present invention. Once pressure in the interior volume 415 of the reservoir 410 has been sufficiently equalized, the user may connect the reservoir assembly 402 with the base assembly 404. When the user connects the reservoir assembly 402 with the base assembly 404, the mating piece 435 may push the flapper valve 440 against the port 412 to close or block the port 412, such that fluidic media in the interior volume 415 of the reservoir 410 can no longer flow out the port 412 to the chamber 450. The needle 430 pierces the flapper valve 440 to allow fluidic media contained in the interior volume 415 of the reservoir 410 to flow through the needle 430 to the base assembly 404 and then to the user. For example, fluidic media could flow from the interior volume 415 of the reservoir 410 through the needle 430 into a fluid path (such as 190 in FIG. 7A) in the base assembly 404 and to the user by way of a cannula (such as 194 in FIG. 7A).

The mating piece 435 may securely hold the flapper valve 440 against the port 412 to prevent the flapper valve 440 from opening while the reservoir assembly 402 and the base assembly 404 are connected. In some embodiments of the present invention, the mating piece 435 may seal off the chamber 450, thus inhibiting fluidic media contained in the chamber 450 from flowing back into the interior volume 415 of the reservoir 410 or otherwise flowing out of the chamber 450.

FIG. 11A illustrates a cross-sectional view of a system 500 for equalizing pressure in a first position in accordance with an embodiment of the present invention. The system 500 may include, but is not limited to, a reservoir assembly 502 and a base assembly 504. The reservoir assembly 502 may include a reservoir 510 having a port 512 and a cap 540. The base assembly 504 may include a needle 530 and a mating piece 535. The reservoir 510 may have an interior volume 515 for containing fluidic media, such as, but not limited to, insulin. The port 512 may be an outlet for expelling fluidic media from the interior volume 515 of the reservoir 510 before the mating piece 535 and the reservoir 510 are operatively engaged. The mating piece 535 and the reservoir 510 may be operatively engaged when the user connects the reservoir assembly 502 with the base assembly 504.

The cap 540 may be located on the port 512 of the reservoir 510. The cap 540 may be loosely fitted on the port 512 to allow fluidic media in the reservoir 510 to push against the cap 540 and lift the cap 540 from the port 512 and flow out the interior volume 515 of the reservoir 510. In other embodiments, such as the embodiment shown in FIG. 11A, the cap 540 may be positioned relatively offset to the port 512 so that fluidic media may flow freely through the port 512. The cap 540 may be pierceable by the needle 530. The needle 530 may be supported by the mating piece 535 and positioned to pierce the cap 540 when the user connects the reservoir assembly 502 with the base assembly 504 allowing the needle 530 to enter the interior volume 515 of the reservoir 510 to establish a fluid path between the reservoir assembly 502 and the base assembly 504. The cap 540 may be held against the port 512 by the mating piece 535, thus closing the port 512 when the user connects the reservoir assembly 502 with the base assembly 504.

In some embodiments of the present invention, the system 500 may further include a structure 555 having a chamber 550. The chamber 550 of the structure 555 may be connected to the port 512 of the reservoir 510. In other embodiments, the chamber 550 may be connectable or otherwise in flow communication with the interior volume 515 of the reservoir 510. For example, when the cap 540 is lifted from the port 512 to allow fluidic media to be expelled from the interior volume 515 of the reservoir 510, a fluid path may be established from the interior volume 515 of the reservoir 510 to the chamber 550. The chamber 550 may have an interior volume for collecting fluidic media expelled through the port 512 from the interior volume 515 of the reservoir 510 before the mating piece 535 and the reservoir 510 are connected or otherwise operatively engaged. Fluidic media may be expelled from the reservoir 510 before the mating piece 535 and the reservoir 510 are operatively engaged in a case where a pressure difference exists between the interior volume 515 of the reservoir 510 and the chamber 550. The structure 555 having the chamber 550 may be located outside of the reservoir 510, for example, the chamber 550 may be adjacent to the reservoir 510. In other embodiments of the present invention, the structure 555 having the chamber 550 may be located within the reservoir 510.

As shown in FIG. 11A, the port 512 of the reservoir 510 may be initially in an open position, such that fluidic media expelled from the interior volume 515 of the reservoir 510 to equalize pressure within the interior volume 515 of the reservoir 510, can flow freely or bolus through the port 512 into the chamber 550. In some embodiments, the expelled fluidic media may push against the cap 540 to move the cap 540 from the port 512 allowing fluidic media to flow out of the interior volume 515 of the reservoir 510 until pressure in the interior

volume 515 of the reservoir 510 has been equalized with respect to pressure in the chamber 550.

In further embodiments of the present invention, the structure 555 may include a membrane wall 552, which may comprise an elastomeric material, or the like. The membrane wall 552 may be configured to expand (552' in FIG. 11B) outwardly to increase the interior volume of the chamber 550 in a case where the chamber 550 sufficiently fills with fluidic media. The membrane wall 552 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material. In yet further embodiments of the present invention, the structure 555 may have an opening (not shown) for purging fluidic media collected in the interior volume of the chamber 550.

FIG. 11B illustrates a cross-sectional view of the system 500 for equalizing pressure in a second position in accordance with an embodiment of the present invention. Once pressure in the interior volume 515 of the reservoir 510 has been sufficiently equalized, the user may connect the reservoir assembly 502 with the base assembly 504. When the user connects the reservoir assembly 502 with the base assembly 504, the mating piece 535 of the base assembly 504 pushes the cap 540 against the port 512 of the reservoir 510 to close or block the port 512. Thus, fluidic media in the interior volume 515 of the reservoir 510 can no longer flow out the port 512 into the chamber 550. The needle 530 pierces the cap 540 to allow fluidic media contained in the interior volume 515 of the reservoir 510 to flow through the needle 530 to the base assembly 504 and then to the user. For example, fluidic media could flow from the interior volume 515 of the reservoir 510 through the needle 530 into a fluid path (such as 190 in FIG. 7A) in the base assembly 504 and to the user by way of a cannula (such as 194 in FIG. 7A).

The mating piece 535 may securely hold the cap 540 against the port 512 to prevent the cap 540 from opening while the reservoir assembly 502 and the base assembly 504 are connected. In some embodiments of the present invention, the mating piece 535 may block or seal off the chamber 550, thus inhibiting fluidic media contained in the chamber 550 from flowing back into the interior volume 515 of the reservoir 510 or otherwise flowing out of the chamber 550.

FIG. 12A illustrates a cross-sectional view of a system 600 for equalizing pressure in a first position in accordance with an embodiment of the present invention. The system 600 may include, but is not limited to, a reservoir assembly 602 and a base assembly 604. The reservoir assembly 602 may include a reservoir 610 having a port 612 and a covering 640 having an opening 642. The base assembly 604 may include a needle 630 and a mating piece 635. The reservoir 610 may have an interior volume 615 for containing fluidic media, such as, but not limited to, insulin. The port 612 may be an outlet for expelling fluidic media from the interior volume 615 of the reservoir 610 through the opening 642 in the covering 640 before the mating piece 635 and the reservoir 610 are operatively engaged. Fluidic media may be expelled from the interior volume 615 of the reservoir 610 before the mating piece 635 and the reservoir 610 are operatively engaged, for example, in a case where a pressure difference exists between the interior volume 615 of the reservoir 610 and a chamber 650 attached to the port 612. The mating piece 635 and the reservoir 610 may be operatively engaged when the user connects the reservoir assembly 602 with the base assembly 604.

The covering 640 may be located on the port 612 of the reservoir 610. The covering 640 may be pierceable by the needle 630. The needle 630 may be supported by the mating piece 635 and positioned to pierce the covering 640 and to

enter the reservoir 610 when the user connects the reservoir assembly 602 with the base assembly 604. Thus, when the reservoir assembly 602 and the base assembly 604 are connected, a fluid flow path is established between the reservoir assembly 602 and the base assembly 604. The opening 642 in the covering 640 may be closed or blocked by the mating piece 635 when the user connects the reservoir assembly 602 with the base assembly 604, such that, for example, fluidic media can no longer flow out the port 612 into the chamber 650.

In some embodiments of the present invention, the system 600 may further include a structure 655 having the chamber 650. The chamber of the structure 655 may be connected to the port 612 of the reservoir 610. In other embodiments, the chamber 650 may be connectable or otherwise in flow communication with the interior volume 615 of the reservoir 610. For example, fluidic media may be expelled from the interior volume 615 of the reservoir 610 through the opening 642 in the covering 640 into the chamber 650. The chamber 650 may have an interior volume for collecting fluidic media expelled through the opening 642 from the interior volume 615 of the reservoir 610 before the mating piece 635 and the reservoir 610 are connected or otherwise operatively engaged. Fluidic media may be expelled from the interior volume 615 of the reservoir 610 before the mating piece 635 and the reservoir 610 are operatively engaged in a case where a pressure difference exists between the interior volume 615 of the reservoir 610 and the chamber 650. The structure 655 having the chamber 650 may be located outside of the reservoir 610. For example, the chamber 650 may be adjacent to the reservoir 610. In other embodiments of the present invention, such as the embodiment illustrated in FIG. 12C, a structure 656 having a chamber 651 may be located within the reservoir 610.

As shown in FIG. 12A, the port 612 of the reservoir 610 may be initially in an open position, such that fluidic media expelled from the interior volume 615 of the reservoir 610 to equalize pressure within the interior volume 615 of the reservoir 610 can flow freely or bolus through the port 612 and the opening 642 in the covering 640. Fluidic media may flow through the port 612 and the opening 642 in the covering 640 until pressure within the interior volume 615 of the reservoir 610 has been sufficiently equalized with respect to pressure in the chamber 650.

In further embodiments of the present invention, the structure 655 may include a membrane wall 652, which may comprise an elastomeric material, or the like. The membrane wall 652 may be configured to expand (652' in FIG. 11B) outwardly to increase the interior volume of the chamber 650 in a case where the chamber 650 sufficiently fills with fluidic media. The membrane wall 652 may also be configured to allow for pressure equalization across it through the use of a hydrophobic or hydrophilic filter or similar material. In yet further embodiments of the present invention, the structure 655 may have an opening (not shown) for purging fluidic media collected in the interior volume of the chamber 650. This may be useful in a case where the interior volume of the chamber 650 is not sufficiently large enough to contain all of the fluidic media expelled from the interior volume 615 of the reservoir 610.

In some embodiments of the present invention, the reservoir 610 may further include a valve 645, such as, but not limited to, a flapper valve or the like. The flapper valve 645 may be located on the opening 642 of the covering 640. The flapper valve 645 may be forced open when fluidic media is expelled from the interior volume 615 of the reservoir 610 to equalize pressure within the interior volume 615 of the reservoir 610 with respect to pressure in the chamber 650. The

flapper valve 645 may be held against the opening 642 by the mating piece 635 when the user connects the reservoir assembly 602 with the base assembly 604, thus closing the opening 642 to prevent fluidic media from flowing out the opening 642 to the chamber 650.

FIG. 12B illustrates a cross-sectional view of the system 600 for equalizing pressure in a second position in accordance with an embodiment of the present invention. Once pressure in the interior volume 615 of the reservoir 610 has been sufficiently equalized, the user may connect the reservoir assembly 602 with the base assembly 604. When the user connects the reservoir assembly 602 with the base assembly 604, the mating piece 635 of the base assembly 604 pushes against the opening 642 of the covering 640 to close or block the opening 642. As a result, fluidic media in the interior volume 615 of the reservoir 610 can no longer flow out the port 612 to the chamber 650. The needle 630 pierces the covering 640 to allow fluidic media contained in the interior volume 615 of the reservoir 610 to flow through the needle 630 to the base assembly 604 and then to the user. For example, fluidic media could flow from the interior volume 615 of the reservoir 610 through the needle 630 into a fluid path (such as 190 in FIG. 7A) in the base assembly 604 and to the user by way of a cannula (such as 194 in FIG. 7A).

The mating piece 635 may securely cover or block the opening 642 to prevent fluidic media from flowing out the opening 642 while the reservoir assembly 602 and the base assembly 604 are connected. In some embodiments of the present invention, the mating piece 635 may close or otherwise seal off the chamber 650, thus inhibiting fluidic media contained in the chamber 650 from flowing back into the interior volume 615 of the reservoir 610 or otherwise flowing out of the chamber 650.

In further embodiments, the needle 630 may be positioned to enter the opening 642 in the covering 640 and to enter the interior volume 615 of the reservoir 610 when the reservoir assembly 602 and the base assembly 604 are connected by the user. In yet further embodiments, the valve 645 may be pierced by the needle 630 when the reservoir assembly 602 and the base assembly 604 are connected by the user. In some embodiments, the needle 630 has a diameter comparable to a diameter of the opening 642 so that the needle 630 seals the opening 642 when the needle 630 enters the opening 642.

The embodiments disclosed herein are to be considered in all respects as illustrative, and not restrictive of the invention. The present invention is in no way limited to the embodiments described above. Various modifications and changes may be made to the embodiments without departing from the spirit and scope of the invention. The scope of the invention is indicated by the attached claims, rather than the embodiments. Various modifications and changes that come within the meaning and range of equivalency of the claims are intended to be within the scope of the invention.

What is claimed is:

1. A system for controlling pressure in a fluid reservoir, the system comprising:

a housing structure having an opening and an interior volume through which a portion of a base assembly may be inserted and received;

a pierceable member having a hollow interior volume, a first end and a second end, the pierceable member arranged in the interior volume of the housing structure, for movement relative to the housing structure from a first position to a second position, the pierceable member arranged to receive a force from the portion of a base assembly to move the pierceable member from the first position to the second position, when the portion of the

base assembly is inserted through the opening and received within the interior volume of the housing; and a hollow needle arranged to be connected in fluid flow communication with the fluid reservoir, the hollow needle having a longitudinal dimension and a piercing end arranged within the hollow interior volume of the pierceable member when the pierceable member is in the first position, the piercing end of the hollow needle piercing through the first end of the pierceable member when the pierceable member is moved from the first position to the second position;

the interior volume of the pierceable member configured to receive fluid from the hollow needle in response to an increase in fluid pressure within the fluid reservoir before the hollow needle pierces through the first end of the pierceable member.

2. A system as recited in claim 1, wherein the pierceable member has an inner surface surrounding the hollow interior volume of the pierceable member, the inner surface of the pierceable member extending along the longitudinal dimension of the hollow needle and bowing outward to define a concave curvature along the longitudinal dimension of the hollow needle.

3. A system as recited in claim 1, wherein the hollow needle has a first opening arranged within the hollow interior volume of the pierceable member when the pierceable member is in the first position, such that fluid flowing through the hollow needle from the reservoir when the pierceable member is in the first position is expelled through the first opening of the hollow needle and retained within the hollow interior volume of the pierceable member.

4. A system as recited in claim 3, wherein fluid flowing through the hollow needle from the reservoir when the pierceable member is in the second position is expelled through the first opening of the hollow needle to a location outside of the interior volume of the pierceable member.

5. A system as recited in claim 1, wherein the pierceable member includes a membrane wall that expands to increase the size of the hollow interior volume, in response to an increase in fluid pressure within the hollow interior volume of the pierceable member.

6. A system as recited in claim 5, wherein the membrane wall comprises an elastic material.

7. A system as recited in claim 5, wherein the membrane wall inhibits passage of fluid out from the hollow interior volume of the pierceable member.

8. A system as recited in claim 5, wherein the membrane wall uses a hydrophobic or hydrophilic material to allow for pressure equalization across the membrane wall.

9. A system as recited in claim 1, wherein the housing structure includes a chamber that is outside of the hollow volume of the pierceable member, but in fluid flow communication with the hollow volume of the pierceable member, for receiving fluid from the hollow volume of the pierceable member, upon a the hollow interior volume of the pierceable member receiving a volume of fluid that is greater than the hollow volume of the pierceable member.

10. A system as recited in claim 9, wherein the chamber of the housing structure is arranged to receive fluid from the hollow volume of the pierceable member, upon a volume of fluid expelled from the first opening of the hollow needle into the hollow interior volume of the pierceable member exceeding the hollow volume of the pierceable member.

11. A system as recited in claim 9, wherein the pierceable member has an inner surface surrounding the hollow interior

volume of the pierceable member, the inner surface of the pierceable member extending along the longitudinal dimension of the hollow needle and bowing outward to define a concave curvature along the longitudinal dimension of the hollow needle.

12. A system as recited in claim 9, wherein the hollow needle has a first opening arranged within the hollow interior volume of the pierceable member when the pierceable member is in the first position, such that fluid flowing through the hollow needle from the reservoir when the pierceable member is in the first position is expelled through the first opening of the hollow needle and retained within the hollow interior volume of the pierceable member.

13. A system as recited in claim 12, wherein fluid flowing through the hollow needle from the reservoir when the pierceable member is in the second position is expelled through the first opening of the hollow needle to a location outside of the interior volume of the pierceable member.

14. A system as recited in claim 1, wherein the interior volume of the pierceable member is expandable to increase the size of the hollow interior volume of the pierceable member, in response to an increase in fluid pressure within the hollow interior volume of the pierceable member.

15. A method for controlling pressure in a fluid reservoir, the method comprising:

providing a housing structure having an opening and an interior volume through which a portion of a base assembly may be inserted and received;

supporting a pierceable member in the interior volume of the housing structure for movement relative to the housing structure from a first position to a second position, the pierceable member having a hollow interior volume, a first end and a second end, wherein supporting the pierceable member includes arranging

the pierceable member to receive a force from the portion of a base assembly to move the pierceable member from the first position to the second position, when the portion of the base assembly is inserted through the opening and received within the interior volume of the housing;

arranging a hollow needle to be connected in fluid flow communication with the fluid reservoir, the hollow needle having a longitudinal dimension and a piercing end, wherein arranging the hollow needle further includes arranging the piercing end of the hollow needle within the hollow interior volume of the pierceable member when the pierceable member is in the first position;

piercing through the first end of the pierceable member with the piercing end of the hollow needle when the pierceable member is moved from the first position to the second position; and

receiving fluid in the interior volume of the pierceable member from the hollow needle, in response to an increase in fluid pressure within the fluid reservoir before the hollow needle pierces through the first end of the pierceable member.

16. A method as recited in claim 15, wherein the pierceable member has an inner surface surrounding the hollow interior volume of the pierceable member, the method further comprising bowing outward the inner surface of the pierceable member that extends along the longitudinal dimension of the hollow needle to define a concave curvature along the longitudinal dimension of the hollow needle.

17. A method as recited in claim 15, further comprising arranging a first opening in the hollow needle within the hollow interior volume of the pierceable member when the

pierceable member is in the first position, such that fluid flowing through the hollow needle from the reservoir when the pierceable member is in the first position is expelled through the first opening of the hollow needle and retained within the hollow interior volume of the pierceable member.

18. A method as recited in claim 17, arranging the first opening in the hollow needle in a location outside of the interior volume of the pierceable member when the pierceable member is in the second position so that fluid flowing through the hollow needle from the reservoir when the pierceable member is in the second position is expelled through the first opening of the hollow needle to the location outside of the interior volume of the pierceable member.

19. A method as recited in claim 15, further comprising providing the pierceable member with a membrane wall that expands to increase the size of the hollow interior volume, in response to an increase in fluid pressure within the hollow interior volume of the pierceable member.

20. A method as recited in claim 19, wherein the membrane wall comprises an elastic material.

21. A method as recited in claim 19, further comprising using hydrophobic or hydrophilic material for the membrane wall to allow for pressure equalization across the membrane wall.

22. A method

as recited in claim 15, further comprising providing a chamber in the housing structure, the chamber being outside of the hollow volume of the pierceable member, but in fluid flow communication with the hollow volume of the pierceable member, for receiving fluid from the hollow volume of the pierceable member, upon a the hollow interior volume of the pierceable member receiving a volume of fluid that is greater than the hollow volume of the pierceable member.

23. A method as recited in claim 22, further comprising arranging the chamber of the housing structure to receive fluid from the hollow volume of the pierceable member, upon a volume of fluid expelled from the first opening of the hollow needle into the hollow interior volume of the pierceable member exceeding the hollow volume of the pierceable member.

24. A method as recited in claim 22, further comprising providing the pierceable member with an inner surface surrounding the hollow interior volume of the pierceable member, the inner surface of the pierceable member extending along the longitudinal dimension of the hollow needle and bowing outward to define a concave curvature along the longitudinal dimension of the hollow needle.

25. A method as recited in claim 22, further comprising arranging a first opening of the hollow needle within the hollow interior volume of the pierceable member when the pierceable member is in the first position, such that fluid flowing through the hollow needle from the reservoir when the pierceable member is in the first position is expelled through the first opening of the hollow needle and retained within the hollow interior volume of the pierceable member.

26. A method as recited in claim 25, wherein fluid flowing through the hollow needle from the reservoir when the pierceable member is in the second position is expelled through the first opening of the hollow needle to a location outside of the interior volume of the pierceable member.

27. A method as recited in claim 15, further comprising expanding the interior volume of the pierceable member in response to an increase in fluid pressure within the hollow interior volume of the pierceable member.